



Legal and Operational Guide for Free Medical Clinics

Co-published with the American Medical Association Foundation

This guidebook was made possible by the generosity of the American Medical Association Foundation and AHLA's Public Interest Donors.





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—from a declaration of the American Bar Association

FOREWORD

The Free or Charitable Medical Clinic continues to serve as an important safety net for millions of under- and uninsured individuals throughout the country. Such clinics are often staffed by volunteer physicians, nurses, and other health care providers who provide primary health care services to those who have limited or no access to health care providers or prescription care, and to indigent populations, including the homeless, undocumented persons, Medicaid recipients. Some clinics are even equipped to provide additional health services, such as basic dental, vision, and behavioral health care services.

Implementation of the Patient Protection and Affordable Care Act (ACA) will not diminish the need for Free Medical Clinics. In fact, the non-partisan Congressional Budget Office estimates that anywhere from 29-31 million Americans will remain uninsured following full implementation of the ACA, largely because they are unable to afford care; they are undocumented immigrants; or they are eligible for Medicaid but reside in a state that chose not to expand the Medicaid program. Additional millions will continue struggling to access health care because of long-standing barriers that existed long before the ACA became law, such as lack of transportation options, poor health literacy, high cost of medications, and lack of dental and mental health care access.

The American Health Lawyers Association (AHLA) recognized the need for a resource that community and health care leaders can use in their efforts to build a Free or Charitable Medical Clinic so that under- and uninsured populations might have improved and regular access to primary health care services. While local and state laws governing the establishment and operation of clinics vary, **The Legal and Operational Guide for Free Medical Clinics** will give clinic organizers a broad understanding of the numerous and most commonly encountered legal and operational issues that must be taken into consideration, such as the scope of services to be provided; funding sources; 501(c)(3) tax-exemption; recruitment and licensure of medical volunteers; insurance coverage and liability; prescription drug management; patient privacy; and quality of care and other patient care issues.

This resource was made possible by the generosity of the American Medical Association Foundation, the National Association of Free and Charitable Clinics, AHLA's volunteer-authors who contributed their time and expertise, and AHLA's Public Interest Donors. It is our sincere hope that this valuable resource will have an impact on helping community leaders and health care providers turn the idea of building and operating a Free Medical Clinic into reality. For the millions who will struggle accessing primary health care services on a regular basis, the Free Medical Clinic will be one of the most important safety nets that continues to positively impact their overall quality of life.

TABLE OF CONTENTS

PART I

THE FREE MEDICAL CLINIC: KEY ISSUES

CHAF	PTER 1: An Overview	
A.	Introduction	11
В.	Impact of the Affordable Care Act	11
C.	. Typical Patient Population	13
D.	Scope of Services	13
	1. Primary Care	14
	2. Mental and Behavioral Health	14
	3. Dental	14
E.	Staff and Personnel	14
F.	Tax Exemption	15
G.	Funding and Support	
	1. Sponsorship	
	2. Fundraising	16
	3. Grants	16
	4. Unrelated Business Income Tax	16
	5. Donated Supplies	18
	RT II RT-UP ISSUES	
CHAF	PTER 2: Structuring a Free Medical Clinic	
A.	Incorporating as a Nonprofit Under State Law	19
В.	Operating as Part of Another Tax-Exempt Organization	20
C.	Articles and Bylaws	22
	1. The Organizing Document	22
	2. Bylaws	22
	3. Governance Issues	
	4. Directors and Officers	25
D.	Medical Direction	28
	Obtaining 501(c)(3) Tax-Exempt Status	

F.	- Application for Recognition of Exemption	29
	1. Completing Form 1023 or 1023-EZ	32
	2. Schedule A	35
G	G. Tax-Exempt Status Under State Law	37
CHA	APTER 3: State Laws on Licensure and Other Authorizations	
	A. Licensure of the Free Medical Clinic	40
•	1. Student-run Clinics	
	Nurse Practitioner-led Clinics	
В	3. Licensure of Medical Volunteers	
	1. Physicians	
	2. Nurses (NPs, LPNs, and RNs)	
	3. Mental Health Professionals	
	4. Social Workers and Clergy	
	5. Physician Assistants	
	6. Pharmacists	
	7. Dentists	45
	8. Specialized Services	
С	C. Credentialing and Privileging	
	D. Deemed Status Under the Federal Tort Claims Act	
Ε	E. Pharmacy Distribution Licensure	50
	Federal and State Regulations	
	2. Narcotics	
F.		
CHA	APTER 4: Limiting Liability	
Α	A. The Good Samaritan and an Analysis of Existing Laws	51
	1. Persons Covered	52
	2. Circumstances	52
	3. Standard of Care	53
	4. Required Conduct	53
	5. Covered Procedures	55
В	3. Federal Tort Claims Act	55
	1. Liability Coverage Under the FTCA	55
	2. Deemed Employees	
	3. Program Requirements	
	4. Qualifying Health Services	58

C.	The Volunteer Protection Act of 1997	.59
D.	Charitable Immunity Laws	.61
	1. Liability Limitations	.61
	2. Conditioning Free Services on Ability to Pay	.62
	3. Other Laws	.64
СНАБ	PTER 5: Insurance Coverage	
	Property and Casualty	64
	Slip and Fall	
	Directors and Officers	
	General Liability (Tortious Claims, Personal Injury)	
	Worker's Compensation	
F.	Equipment Breakdown and Computer Coverage	
G.	Commercial Crime Insurance	
H.	Umbrella Insurance	.68
СНАБ	PTER 6: Clinic Space	
	Leasing and Space Considerations	68
	Rent	
	Lease Compliance and Security	
	The Americans with Disabilities Act	
	1. Physical Barriers	
	2. Language/Communication Barriers	
ΡΔΕ	RT III	
OPE	ERATIONAL ISSUES	
CHAF	PTER 7: Recruiting and Training	
	Medical Professionals	.73
	Management Staff	
	Training	
D.	Affiliation with Health Occupational Schools	.75
СНДЕ	PTER 8: Operating the Clinic	
	Hours of Operation	.76
	Limited English Proficiency and Interpreters	
	Background Checks	

CHAPTER 9: Patient Care Issues A. Patient Intake......78 B. Patient History and Reliability of Patient Records79 C. Terminating the Patient Relationship81 D. Prescription Drug Management......82 1. Acceptable Ways to Obtain Prescription Drugs82 2. Security of Drugs83 3. License to Distribute Drugs84 4. Record Keeping and Inventory Management84 5. Affordable Prescription Drug Assistance Programs86 CHAPTER 10: Patient Privacy and Record Keeping A. Establishing the Medical Record87 B. Privacy and Confidentiality88 1. The Health Insurance Portability and Accountability Act......88 3. The Privacy Rule88 4. The Security Rule89 5. The Breach Notification Rule89 6. The Enforcement Rule......89 7. Alcohol and Drug Abuse Records......89 8. State Privacy Laws......90 C. Mandatory Reporting91 D. Medical Record Practices92 E. Responding to Record Requests by Other Providers......92 Receiving Continuity of Care Documents from Other Providers......92 G. Responding to Record Requests by Law Enforcement Agencies92 1. Court Orders, Warrants, Subpoenas, and Summons93 2. Administrative and Investigative Subpoenas......93 3. Locating Certain Persons and Reporting Crimes93 4. Prevention of Physical Harm......96 5. Inmates in Custody96 6. Specialized Government Functions......96 7. Medical Examiners and Coroners......96 8. Sensitive Health Information96 H. Worker's Compensation......98 The Family Medical Leave Act98

J.	The Americans with Disabilities Act	99
K.	Record Retention, Storage, and Destruction	99
CHAF	PTER 11: Quality of Care and Patient Safety	
A.	Medical and Nursing Oversight	102
	1. Supervisory Hierarchy	
	2. Staff Meetings and Continued Training	102
	3. Specialists Performing Primary Care Services	104
	4. Coordinating Care with Social Workers and Behavioral Health Providers	105
	5. Collaborative Practice Agreements for Physician Extenders	106
B.	Quality of Care Review Issues	108
	1. Medical Records	108
	2. State Medical Peer Review Laws	110
C.	Clinic Protocols	111
D.	Continuity of Care	112
	1. Collaborating with Local Hospital Emergency Departments	112
	2. Education and Marketing	113
	3. Access to Emergency Room Records	114
	4. Missed Appointments	115
	5. Reducing Wait Times	117
E.	Working with Other Providers and Collaborating for Affordable Care	118
F.	Potential Issues and Protections Under the Anti-Kickback Statute	
G.	-9	
Н.	, ,	
l.	Security Issues for Staff and Patients	
	OSHA Standards and Violence	121
	2. Coordinating with Law Enforcement and the Use of Crime	
	Detection Systems	122
PAF	RT IV	
	DITIONAL RESOURCES	
A.	Website Links to Governmental and Non-governmental Organizations	
	Associated with Free Medical Clinics	124
В.	Appendices—Sample Forms	A1-l1

Appnedix A— Clinic BylawsA1		
Appendix B— Employee ManualB1		
Appendix C—Harrassment Policy		
Appendix D—Executive Director Job Description		
Appendix E— Nurse Job DescriptionE1		
Appendix F— Model COBRA Continuation of Coverage F1		
Appendix G—Collaborative Practice Agreement		
Appendix H— Comparison of Free & Charitable Clinics to		
Federally Funded ClinicsH1		
Appendix I— Donation Flyer		
C. Endnotes		
D. Factoid Sources		
PART V		
ACKNOWLEDGEMENTS		
1. Authors and Contributors149		
2. Public Interest Donors153		



PART I

THE FREE MEDICAL CLINIC: KEY ISSUES

CHAPTER 1: An Overview

A. Introduction

The Free Medical Clinic, often referred to as Free or Charitable Clinics, is a health care community safety net that is established, operated, and maintained for the purpose of providing primary health care to socioeconomically and geographically underserved patient populations.¹ Typically, the Free Medical Clinic's personnel includes dedicated volunteers and/or paid staff who provide medical, dental, pharmacy, vision, and/or behavioral health services to individuals who otherwise would not be able to afford such services.²

Free Medical Clinics can be organized under the Internal Revenue Code (IRC) as 501(c)(3) tax-exempt organizations, meaning they are organized and operated only for the charitable, religious, educational, and/or scientific exempt purposes set forth in the Code. The term "charitable" is defined by the Internal Revenue Service (IRS) to include "relief of the poor, the distressed, or the underprivileged, etc." Charitable organizations are prohibited from operating for the benefit of private interests and are eligible to receive tax-deductible contributions. In addition, Free Medical Clinics, if not organized as a 501(c)(3) on their own, can operate under or as an affiliate of another 501(c)(3) organization.

The Free Medical Clinic is not required to provide services free of charge to be classified as a charitable entity. It may charge a nominal fee as long as the necessary services are rendered without consideration of the patient's ability to pay. Because Free Medical Clinics serve those who could not otherwise afford medical services, the Clinics often limit their services to patients who do not have insurance, have limited insurance, and/or have limited or no access to necessary health care.

B. Impact of the ACA on Free Medical Clinics

Fewer individuals may remain uninsured (and therefore ineligible for Free Medical Clinic services) as a result of the Patient Protection and Affordable Care Act (ACA). However, numerous barriers to health care access will continue to exist for many, such as the homeless population who do not have the resources to apply for coverage under the ACA's health care exchanges, or undocumented individuals who are not eligible for ACA coverage. The Congressional Budget Office stated that anywhere from 29-31 million people will remain without access to health care after the ACA's implementation.⁷ This number includes documented

and undocumented individuals, as well as "those who are eligible for Medicaid but reside in states that are not going to expand [their Medicaid] program." This illustrates the ongoing need for Free Medical Clinics to continue treating seriously disadvantaged communities that have fallen through the cracks. Such Clinics may want to consider offering resources that will help eligible patients apply for and receive health care coverage through Medicaid or health insurance exchange. The National Association of Free & Charitable Clinics (NAFC) encourages Free Medical Clinics to remain aware of the challenges facing the underserved and be prepared to help those who, due to issues of affordability, accessibility, or even the "[p]ortability of primary, specialty, dental care and medication access," remain unable to access traditional health care services.

Clinics located in states that have expanded Medicaid may find that certain business and operational models will help them maintain their charitable missions while remaining financially viable, allowing providers to preserve the medical home for current patients who may no longer qualify for free care after implementation of the ACA, which is particularly important in areas that experience a shortage of Medicaid providers or in instances where patients move in and out of Medicaid eligibility status due to inconsistent employment or changes in family status.



C. Typical Patient Population

Free Medical Clinics provide services to low-income adults who are under- or uninsured (not covered by Medicare, Medicaid, or other government program) and are residents of the county in which the Clinic is located. Nationwide, a majority of Free Medical Clinics see patients who are at 100%-300% of federal poverty level (FPL). In the state of Ohio, for example, Clinics typically require the individual's income to be at or below 200% of FPL to be considered low income.¹⁰

Table 1 shows the federal poverty guidelines for 2014 depending on family size.¹¹ Eligibility requirements can vary from clinic to clinic based on the community's specific needs.¹² For example, some Clinics treat all ages,¹³ while others provide services to those who have inadequate health insurance coverage¹⁴ or tailor their services to certain health conditions (e.g., HIV/AIDS)¹⁵ and ethnic groups.¹⁶

Table 1: 2014 Federal Poverty Guidelines

2014 FPL Guidelines*			
Family Size	200%		
1	\$23,340		
2	\$31,460		
3	\$39,580		
4	\$47,700		
5	\$55,820		
6	\$63,940		
7	\$72,060		
8	\$80,180		
*Add \$8,120/person for families over 8			

D. Scope of Services

Most Free Medical Clinics provide a wide variety of primary health care services to eligible patients. Depending on available resources, some clinics may also provide basic dental and mental and behavioral health services.

1. Primary Care

Free Medical Clinics provide primary care for minor, non-life threatening illnesses and injuries and should not be a substitute for emergency medical care. While specific services vary from clinic to clinic, most conduct general physical exams¹⁷ and provide testing and treatment for chronic conditions (e.g., diabetes and high blood pressure)¹⁸ and minor medical problems (e.g., headaches, sore throats, cough/colds, stomach issues).¹⁹ Some Clinics may also provide prescription assistance programs and/or other pharmacy services and certain gynecological services.²⁰ When possible and if Clinic resources allow, the Clinic may be able to provide a referral if it is unable to diagnose or treat a patient's problem.²¹

2. Mental and Behavioral Health

To the extent funding and the essential volunteers are available, Free Medical Clinics can provide a range of mental and behavioral health services, including screening to identify at least one mental health concern; assessment and diagnosis; medication management; mental health counseling; and case management. According to a survey conducted by AmeriCares, "few [Clinics] conduct universal screening to practively identify patients with undetected mental illness." However, when a Clinic can conduct unversal screening, alcohol and substance use are the conditions most often universally screened for, followed by depression and anxiety.²²

3. Dental

Clinics that have the resources to offer dental services typically provide routine exams and assessments, cavity fillings, teeth cleanings, tooth extractions, and x-rays. Certain Clinics may also provide select root canal, sealant, and fluoride treatments. Free Medical Clinics generally do not provide dentures or partial dentures, crown or bridgework, implants, braces, teeth whitening, or wisdom tooth extractions. Some states work with their state dental associations or through a dental health coalition to provide primary dental care to Clinic patients.²³

E. Staff and Personnel

A Free Medical Clinic's staff typically includes a mixture of volunteer physicians, licensed health care professionals, and other non-licensed medical personnel such as lay volunteers. ²⁴ Board-certified physicians who typically devote approximately one to four half-day sessions each month are the most frequent types of volunteers. Nurses, nurse practitioners, physician assistants and, to a smaller extent, social workers and psychologists also volunteer at Free Medical Clinics. According to a 2010 study, Clinic volunteers devoted an average of 4,237 hours or 2.4 volunteer hours per patient annually. More than 75% of Free Medical Clinics use paid staff in addition to volunteers, and approximately half pay their administrative staffs. Nearly two-thirds employ a paid executive director. ²⁵



F. Tax Exemption

The majority of Free Medical Clinics are volunteer-based, safety-net health care organizations that provide health care services to predominantly uninsured and economically disadvantaged individuals²⁶ and, therefore, operate either as standalone charitable tax-exempt organizations, a program component or affiliate of another charitable organization, or as a standalone organization using community funds and donations. Operating as a 501(c)(3) tax-exempt organization or as a component or affiliate of another charitable organization is a popular financial model because most foundations and government agencies award grants only to charitable entities. In fact, 501(c)(3) organizations receive approximately one-third of their financial support from the general public, unit of government, or organization formed to raise money for a specific supported charity.²⁷ If Clinic organizers wish to have their Clinic designated as a 501(c)(3) charitable organization, they must form a new nonprofit organization by incorporating as a nonprofit entity under applicable state laws and obtain tax-exempt status from the IRS. Corporation regulations are state-specific, so Clinic organizers should refer to state law to better understand the relevant jurisdictional requirements.

G. Funding and Support

1. Sponsorship

Free Medical Clinics can be sponsored by individuals or organizations such as hospitals, medical associations, secular community organizations, faith-based entities, and foundations established as a result of a hospital sale. A Clinic's sponsor will often define the character of the Clinic and impact the services it provides. For example, a Free Medical Clinic that has a faith-based sponsor may pursue a religious mission or follow a set of religious principles while simultaneously working to see that health care is provided to underserved populations.²⁸

2. Fundraising

Free Medical Clinics are often supported through charitable donations and typically receive little or no regular government support. Rather, they raise funds by securing grants and donations from community through annual fundraising drives and outreach to individuals, businesses, foundations, and other organizations. When accepting contributions, the Clinic should make sure the contribution is "designated to or for the use of" a charitable organization under IRC Section 170(a). Designated funds are charitable contributions with the stipulation that they be used for a specified purpose (i.e., an approved project or program).²⁹ Such designation permits the donor to earmark his or her contribution to the FMC for a particular use without jeopardizing the charitable deduction, provided the restriction does not prevent the Clinic from freely using the transferred assets or, at a minimum, the income therefrom, in furtherance of its charitable purposes. If the gift is earmarked for a non-charitable purpose or for a charitable purpose outside the Clinic's charitable mission, the gift will not be deductible.³⁰ Free Medical Clinics should, therefore, adopt a written policy governing all designated or restricted gifts. Clinics should require board approval of restricted gifts that are not within the Clinic's previously approved mission and encourage the use of suggested donations instead of legally binding designations or restrictions.

3. Grants

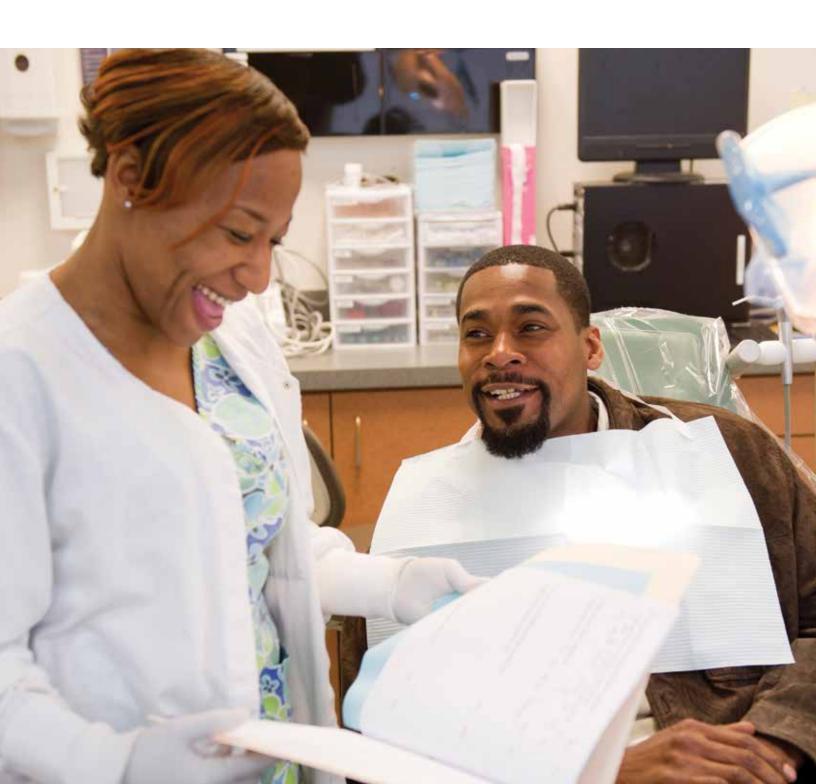
Grants from businesses, foundations, and government organizations can be major sources of funding that help establish services and support ongoing programs where communities and governments share a common interest. These grants typically require a grant proposal, budget, and narrative, as well as compliance with the terms of the grants and any related agreements.

4. Unrelated Business Income Tax

Tax-exempt charitable organizations are generally not required to pay income tax. However, income from certain activities may still be taxable under federal or local law. Of particular concern is the tax that a charitable organization may have to pay on income derived from a regularly carried out trade or business that is not substantially related to the organization's

exempt purpose (an "unrelated business income tax" or UBIT). The operation of a retail grocery store, for example, staffed by paid employees, could generate income for an FMC that would be subject to UBIT.

Numerous registration and reporting requirements under federal and state law exist in connection with fundraising activities. Certain fundraising activities, such as online sales or auctions, may be considered unrelated business activities if regularly carried out by the



charitable organization. To protect its tax-exempt status, the Free Medical Clinic should avoid dedicating a substantial part of its time or resources to unrelated activities and be prepared to pay UBIT unless an exception applies.

Keep in mind, however, that income-generating activities that are structured to further one or more of the charitable organization's exempt purposes will not be subject to UBIT. For example, if the charitable organization's unrelated business activity utilizes a volunteer workforce, sells donated merchandise, or conducts bingo or similar activities, the organization may be able to avoid paying tax on such income. To illustrate by using the aforementioned example, an organization's operation of a retail grocery store that is almost fully staffed by youth as part of a therapeutic and training program to help disadvantaged youth is not likely to constitute an unrelated business activity because the store is operated to further the charity's exempt purpose of assisting disadvantaged youth.³¹

5. Donated Supplies

Donors and charitable organizations must comply with a number of substantiation requirements regarding the donation of goods and services. Generally, charitable organizations must provide written disclosure to a donor who has received goods or services in exchange for a contribution that exceeds \$75. For donations of any amount, a donor will need either written acknowledgement from the charitable organization or a bank record, such as a cancelled check or credit card statement, to claim the deduction. In addition, a donor must obtain a written acknowledgement for any single contribution of \$250 or more if he or she wishes to claim the donation as a deduction.³²

In the context of the Free Medical Clinic, the Clinic may want to approach other organizations with similar missions for donations during the start-up phase. For instance, a local hospital may be willing to provide radiology services, local businesses may donate office equipment and supplies, and physician offices or other health care facilities may be able to donate used exam tables, furniture, dental equipment, and extra medical supplies.

Pharmaceutical companies may also offer assistance programs for the drugs they manufacture. These programs generally provide prescription medications for free or at a greatly reduced cost to patients who otherwise would not be able to afford them. Free Medical Clinics can either receive and distribute the medications directly to the patient; verify that the patient is eligible for the program and subsequently confirm that the medication is shipped to the patient; or determine whether the patient can receive the medication from a local pharmacy. Many Free Medical Clinics try to help patients qualify for these drug assistance programs.

PART II

START-UP ISSUES

CHAPTER 2: Structuring a Free Medical Clinic

A. Incorporating as a Nonprofit Under State Law

Incorporation is governed by state law, and the choice of entity for a particular organization will be subject to the laws of the state in which it is registered. Depending on the choice of entity, the organization's leaders may be protected from liability or be subject to limited liability. The organization may also qualify for certain tax benefits, including tax exemption. In the event an organization intends to receive financial support through charitable donations, government funding, or public and private grants, it should be incorporated as a nonprofit corporation. Incorporating as a nonprofit confers some benefits, but subjects the entity to certain restrictions as well. Listed below are some of the benefits and challenges of operating as a nonprofit:³³

Benefits:

- ♦ Liability Protection—The governing board and the corporation's officers are protected from liability that may arise from the corporation's activities. In addition, organizers, directors, officers, and employees may not be held personally liable for the corporation's debts. Individuals may be held personally liable, however, when acting outside the scope of their duties to the corporation. The corporation's liability is limited to the corporation's assets.
- ♦ Tax-Exempt Status—While the formation of a nonprofit corporation does not automatically qualify the organization for tax-exempt status, the organization will benefit from tax-exempt recognition if it applies for and meets the requirements under applicable federal and state laws.
- Increased Fundraising Potential—Obtaining 501(c)(3) status increases the organization's opportunity to obtain such funding and support. If the corporation secures 501(c)(3) tax exemption, donors may deduct their donations to the organization, which can incentivize individual and corporate contributions and bolster fundraising efforts. In fact, many state and federal agencies and charitable foundations will only donate grants and other funding to 501(c)(3) organizations.

Challenges:

- ♦ Cost—Forming a nonprofit corporation can be time-consuming, labor-intensive, and costly. State requirements, such as preparing articles of incorporation and bylaws and applying for tax exemption take time, money, and resources.
- Record-keeping—Tax-exempt nonprofits are required to keep detailed records and submit annual filings to the state and IRS by specific deadlines to maintain its active tax-exempt status.
- Oversight and Accountability—Once an organization is formally organized as a nonprofit corporation, personal control over the corporation becomes limited because the corporation is now subject to state and federal laws and regulations, as well as the nonprofit corporation's own articles of incorporation and bylaws. Some states require nonprofits to be governed by a board of directors that elects or appoints the officers who set the corporation's policies and procedures.
- Public Scrutiny—A nonprofit corporation is dedicated to the public interest; therefore, its state and federal filings are part of the public record and are open to public inspection. The public may obtain copies of state and federal filings to learn about salaries and other expenditures.

B. Operating as Part of Another Tax-Exempt Organization

To streamline the time-consuming and costly process of creating a tax-exempt nonprofit entity, a Free Medical Clinic may want to consider operating as part of another organization that has already secured 501(c)(3) status, which will give the Clinic access to the organization's existing resources, including staff, office space, technology, and equipment. In addition, established organizations that have earned a good reputation in the local community may provide an affiliated Clinic with valuable credibility it may need as a new and independent organization.

As a tradeoff, however, an affiliated Clinic may lose the autonomy that an independent Clinic provides. The affiliated Clinic's policies and plans will have to align with the parent organization's charitable purpose, and the Clinic's leadership will be subject to the oversight and authority of the parent organization's board of directors. If the Clinic's leadership is willing to make such concessions, affiliation with an established institution may streamline the start-up process and allow the new Clinic to open sooner.



C. Articles and Bylaws

1. The Organizing Document

To create a nonprofit corporation, most states require that an organizing document, such as the articles of organization (or incorporation), be filed with the state's Secretary of State. State statutes set forth the required information that must be included in the organizing document. In addition, certain language should be included to comply with IRS requirements for tax exemption as outlined in IRS Publication 557.³⁴

Generally, states require that the organizing document include at minimum the organization's name and its registered location for service of process purposes. The IRS mandates that the organizing document contain the organization's charitable purpose and a description of operational restrictions, such as restrictions on lobbying and private inurement of the organization's earnings. Additional information that the organization may choose to include, if not required by state law, are (1) the names of the organization's incorporators and leadership, including the board of directors; (2) a statement of personal liability so that organization leaders may avoid personal liability for acting reasonably and in good faith as an agent of the organization; and (3) the duration of the organization's corporate existence and how its assets may be distributed upon dissolution. Many states have samples of organizing documents that comply with statutory requirements on the Secretary of State's website. Small business organizations may also have template documents available online.

2. Bylaws

Bylaws are the formal rules and procedures under which an organization and its board of directors operate. An organization's bylaws should be drafted to comply with state law while also remaining consistent with the articles of incorporation or other organizing document. They should provide sufficient direction to the board so that the organization can operate efficiently, but not be so restrictive that they hinder or constrain operations. Because a vote by the board is generally required to amend bylaws, day-to-day operational practices that may be subject to change on a frequent or as-needed basis should be governed by separate policies and procedures.

a. General Information

The bylaws should comply with state statutory requirements and generally include the organization's name; type of legal entity; address for its principal place of business and registered office; and its registered agent. The bylaws also should state the organization's mission and charitable purpose as a 501(c)(3) entity.

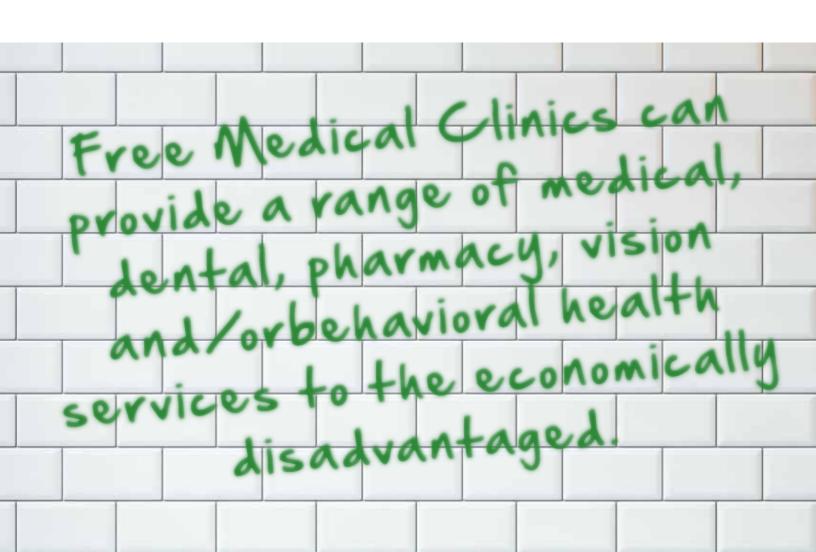
b. Members

If the organization has any members other than the board of directors, the bylaws should describe the members' duties, privileges, and rights, which may include voting rights if granted by the board. The bylaws also should address how such members are appointed, the duration of their terms, and how they may be removed.

c. Board of Directors

The bylaws should include the following information regarding an organization's board of directors:

- Makeup, including any special requirements that may exist such as having community representatives from various industries or representation from the organization's target population;
- ♦ Powers and duties with respect to the organization's operations;
- ♦ Officers' titles and a description of their duties;



- ♦ The process for electing and removing officers;
- Number of board members and length of terms;
- ♦ Rules for election, the procedures by which a member may resign or be removed, cause for removal, and the process to fill a vacancy;
- The procedure for electing new members, including how voting may be conducted (e.g., electronically, in person, by proxy); quorum requirements; and how many votes are needed to add a member (e.g., a simple majority or 2/3 majority).

d. Meetings

The bylaws should describe how often board meetings are held and include the notice requirements, which set forth the process by which the members are notified of the meeting's purpose, time, and location. Special meetings should also be addressed, including who may call a special meeting and the notice procedure.

e. Committees

If the board of directors has committees, the bylaws generally include the names of each committee, define each committee's duties, explain how members are appointed, and identify the officer(s) to whom each committee reports.

f. Amendments

The bylaws should set forth the procedure by which the board may amend the bylaws. For example, a provision of how bylaws may be amended can be stated as follows:

"Amendments to Bylaws: These Bylaws may only be terminated, amended, or modified upon the affirmative vote or written consent of seventy-five percent (75%) of the outstanding shares of Stock."

3. Governance Issues

Recruiting and engaging community leaders to serve as board members and officers for a Free Medical Clinic will help Clinic organizers understand the needs of their community's vulnerable populations and address existing and potential barriers to health care.

4. Directors and Officers

a. Attributes

Generally, the board of directors is the organization's governing body and is granted the authority to make operating decisions for the organization. Board members should represent the community served, be committed to furthering the organization's objectives, and demonstrate a willingness to take on tasks related to the organization's operations. In the context of the Free Medical Clinic, the board would direct the Clinic's activities and select the managers, staff, and volunteers who will carry out the operations of the Clinic. The board's conduct is governed by the Clinic's bylaws and other corporate documents and must further the Clinic's mission.³⁵

Directors can serve as a bridge between the Clinic and community stakeholders by providing new information to the Clinic, educating the community about the Clinic's mission and goals,³⁶ and maintaining relationships with the Clinic's funding sources.³⁷ One's status in the community and his or her unique skill set should be considered when selecting a member to serve on the Clinic's board of directors as such deliberate and thoughtful selection of board members will add to the Clinic's legitimacy.³⁸

The role, responsibilities, and requirements for board members are governed by applicable state and federal laws. The Department of Health and Human Services Office of the Inspector General (OIG) has published a number of compliance resources for health care boards of directors, including "A Toolkit for Health Care Boards" and "Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors." Under commonly accepted principles of nonprofit law, board members are bound by the general duties of care, loyalty, and obedience.

- The duty of care is the duty to act in a reasonable and informed manner and to discharge duties with the care that an ordinarily prudent person would exercise under similar circumstances. Such conduct generally includes attending meetings, exercising independent judgment, being adequately informed, delegating appropriately, and monitoring and controlling the organization's management staff. In exercising this duty, directors may reasonably rely on information presented by trustworthy sources, including, but not limited to, the organization's officers, employees, and experts, such as accountants and legal counsel.⁴¹
- The duty of loyalty is the duty to act in the organization's best interest rather than to further one's personal or business interests. This duty requires a director to be aware of any conflict of interests and to deal with such conflicts according to applicable state nonprofit corporation laws and IRS procedures. Directors must disclose potential or



actual conflicts and corporate opportunities for the organization in accordance with such requirements. The duty of loyalty also requires a director to keep confidential all matters pertaining to the organization until such matters become public.⁴²

♦ The duty of obedience requires directors to act in accordance with all applicable statutes and the organization's charter. Additional duties may apply under special circumstances.

b. Recruiting Board Members

When recruiting board members from the community, Clinic organizers should be able to clearly articulate the roles they envision for the members of its board. A general job description can include, for example, (1) minimum legal requirements pursuant to applicable law; (2) general board member responsibilities; (3) to whom board members are responsible; (4)

term limits; and (5) necessary qualifications and skills. The board may include a Chair, Vice Chair, Secretary, and Treasurer. Clinic organizers may wish to provide each officer a job description. For example, the Chair of the Free Medical Clinic's board may be responsible for conducting searches for key management staff, while the Secretary is responsible for providing notice of board meetings and votes.⁴³

c. Board Committees

Depending on the size of the board and the complexity of the organization, the board of directors for a Free Medical Clinic may elect to compose committees to which it can delegate certain powers, if permitted by the Clinic's corporate documents. Such board committees may be either ad hoc (convened for a limited purpose) or standing committees that are permanent in nature. An ad hoc committee may be convened to oversee a capital improvement, recruit key management staff, engage the community and maintain public relations or evaluate a major transaction. Standing committees may include an executive committee, strategic planning committee, research committee, fundraising committee, nominating committee, and an audit committee. Committees can be advisory in nature or have the authority to act on behalf of the board. State laws may restrict the ability of a board to appoint non-directors to a committee who can act on behalf of the board.

d. Liability of Directors and Officers

A Free Medical Clinic and its board of directors and officers are subject to being sued for a variety of alleged failures that range from breaching the duty of care, failing to fulfill the Clinic's mission, or having employees and volunteers who fail to conduct themselves within the parameters of the Clinics' mission. State law may limit the Clinic's ability to indemnify directors and officers in case of a lawsuit, so Clinic organizers should consider obtaining advice from legal counsel on how to address such indemnification in the governing documents. A Clinic also is responsible for ensuring that the personal assets of its directors and officers are protected through Director and Officer Liability Insurance.

e. Managers

Managers are under the board's oversight. In accordance with applicable legal requirements, they manage the organization's day-to-day operations. Clinics should have policies and procedures that outline a defined line of authority from the board to the management staff. For instance, a manager's authority to take certain limited action may flow from the organization's bylaws, a resolution of the board or a specific authorization. For example, a resolution of the board that authorizes an annual operating budget might allow a manager to act on the budget, such as choosing the telephone provider, hiring support staff, or executing a lease for Clinic space after the lease has been approved by the board.

D. Medical Direction

A Clinic's leadership must include an individual who provides medical direction on the Clinic's behalf, usually the Medical Director, Clinic Director or Chief Medical Officer. The medical director is responsible for overseeing all Clinic aspects of the care provided at the Clinic, including, but not limited to, supervision of staff, development and implementation of a quality assurance program, quality improvement, and risk management initiatives. The medical director may be an employee or a volunteer, depending on the size and complexity of the Clinic, as long as he or she is qualified and capable of satisfying the role of medical director.

Free Medical Clinics generally focus on providing primary health care services, so a primary care physician or other physician with leadership experience in the Free Medical Clinic environment may be best suited to oversee the health care services provided by the Clinic. If funding is limited, it may be helpful to appoint a medical director who is capable of contributing to the financial oversight and monitoring of the Clinic's operating budget. As with the board of directors and its officers, a Free Medical Clinic should have a position description for the medical director that clearly outlines his or her qualifications, duties, and responsibilities.⁴⁵

E. Obtaining 501(c)(3) Tax-Exempt Status

Organizations that are exempt from federal taxes are described in the United States Internal Revenue Code. The best known type of tax exemption is the 501(c)(3) exemption, also known as the "charitable tax exemption." To be tax exempt under IRC Section 501(c)(3), an organization must be organized and operate exclusively for exempt purposes as set forth in Section 501(c)(3), and none of the organization's earnings may inure to any private shareholder or individual. In addition, the entity cannot be an "action organization" that attempts to influence legislation as a substantial part of its activities, and it may not participate in any campaign activity for or against political candidates. 46 501(c)(3) organizations enjoy many benefits, including, but not limited to the following:

- Exemption from federal and/or state corporate and income taxes for most types of revenue;
- Ability to accept contributions and donations that are tax deductible to the donor;
- Ability to apply for grants and other public or private allocations available only to IRSrecognized 501(c)(3) organizations;
- Potentially higher thresholds before incurring federal and/or state unemployment tax liabilities;

- Public legitimacy of IRS recognition (reputational value);
- ♦ Discounts on U.S. postal bulk-mail rates and other services; and
- Nonprofit incorporation shields owners and managers from personal liability for the group's actions, subject to certain legal exceptions (corporate form), and formalizes the group's goals and helps maintain organizational focus (nonprofit status).

F. Application for Recognition of Exemption

The process for becoming a tax-exempt organization can be lengthy. An organization should therefore give itself at least six months to a year of lead time to apply for tax-exempt status before it begins to operate and solicit financial support. During this time, the organization should collect the information and documents that will help in completing the application, including documents related to the organization's expenses and revenues. Clinic organizers may want to involve those who are familiar with the organization's finances.

- Hire Legal Counsel, Other Professionals—Legal counsel and the counsel of other professionals (e.g., accountants, consultants) will be critical in helping Clinic organizers navigate the numerous ordinances, statutes, and regulations (at the local, state, and federal levels) that will impact the establishment and operation of the Free Medical Clinic. Clinic organizers may find that local attorneys are willing to provide their legal services on a pro bono basis.
- ♦ Choose the Corporation's Name—A nonprofit is typically formed as a corporation and each state has specific naming requirements. Clinic organizers should take care that their corporation's name does not infringe on any assumed name or trademark rights by checking the Secretary of State's database, as well as the database of the U.S. Patent and Trademark Office.⁴⁷
- ◇ Draft and File the Articles of Incorporation—A nonprofit corporation is legally created with the filing of the articles of incorporation or certificate of formation. Articles of incorporation typically identify the limitations on an entity's corporate powers, the entity's name, its purpose(s), and the agent for service of process, (e.g., the name and address of an individual who can receive lawsuits and other official corporation correspondence on behalf of the entity). The requirements vary from state to state, so Clinic organizers should check with their state's Secretary of State for further guidance. Most state websites have sample forms, but they often contain only basic regulatory guidelines and should not be considered as comprehensive guides. For example, a state's sample form may not mention the specific charitable purpose statement required for IRS purposes.

In 1967, The Haight Ashbury Free Clinic in San Francisco treated over 400 patients in its first week of operation:

- Appoint the Board of Directors—If the initial directors are not named in the articles of incorporation, the Clinic should appoint the board through a written resolution. The number of required directors will vary from state to state. For instance, under California law, a nonprofit board may have as few as one director; however, the IRS is unlikely to grant 501(c)(3) status to a nonprofit with only one director. Nonprofits typically have anywhere from 3 to 25 directors.
- Draft the Bylaws and Conflict of Interests Policy—A corporation's bylaws typically include at minimum fundamental provisions regarding the corporation's management of its activities and affairs. Bylaws provide guidance to the board and integrate sound governance practices that align with government authorities, funders, and other interested stakeholders. If the nonprofit has voting members, the bylaws should contain additional provisions about the members' rights and processes. Nonprofits considering a voting membership structure may want to consult with an experienced corporate lawyer, particularly if the nonprofit does not expect its members to actively participate in meetings and regularly exercise their voting rights. The bylaws should separately articulate policies addressing key governance and management issues. For example, although not required by federal tax law, it is considered a best practice for any nonprofit to adopt a conflict of interests policy. A conflict of interests policy and related procedures should "help ensure that when actual or potential conflicts of interest arise, the organization has a process in place under which the affected individual will advise the governing body about all the relevant facts concerning the situation."48 Clinic organizers may wish to consult the sample policy provided in the Instructions to IRS Form 1023 when drafting its conflict of interests policy.49
- Hold a Board Meeting—The board should adopt the bylaws and other corporate policies, elect officers, and finalize other operational matters, such as bank accounts, compensation, and meeting schedules.
- Obtain an Employer Identification Number—After determining what type of organizational structure best fits the organization's mission, and prior to filing its Form 1023 application, the organization will need to obtain an Employee Identification Number (EIN), which is required to obtain the Form 1023 tax-exempt application. An officer or authorized third party designee may apply for and obtain an EIN online. If the organization's contact person is an independent representative, the organization will need to file a Form 2848, Power of Attorney and Declaration of Representative.

Apply for Federal Tax Exemption with the IRS—Completing the Form 1023 application for tax-exempt status may be the most challenging part of the Clinic's startup process. The application is a legally-driven and comprehensive inquiry consisting of eleven Parts and eight Schedules that requires information about the corporation's organizational structure; compensation and other financial arrangements with officers and directors, specifically highly paid employees and independent contractors; members and other individuals and organizations that receive benefits from the organization; organizational history (e.g., an organization that was spun off or previously fiscally sponsored by another organization may need to complete an additional schedule as a successor organization); specific activities to be engaged in by the Clinic; and actual and/or projected statement of revenues and expenses (which should be consistent with any identified activities).

The IRS may typically take three to four months or longer to process a Form 1023 application. The waiting period may be longer if the application contains errors, omissions or other information that requires additional development by a special IRS department. If an organization does not have the required organizational structure, the IRS will return the application without refunding the application fee. If the organization creates the requisite structure within the time specified by the IRS, the organization can resubmit its application without paying an additional fee.⁵⁰

1. Completing Form 1023 or 1023-EZ

A Free Medical Clinic will be required to complete and submit to the IRS either a Form 1023 or a Form 1023-EZ. The traditional Form 1023 is a 26-page application that can be submitted online or via regular U.S. mail.⁵¹ Form 1023-EZ is a short three-page application that must be submitted online (i.e., it cannot be submitted on paper).⁵² It is likely that a Free Medical Clinic will be eligible to use Form 1023-EZ, but should verify with the IRS.

a. Form 1023-EZ

Form 1023-EZ is the streamlined version of Form 1023. To determine if a Free Medical Clinic is eligible to use this application, it must first complete the Form 1023-EZ Eligibility Worksheet, which is part of the Form 1023-EZ Instructions. If the Clinic answers "yes" to any of the questions asked in the Eligibility Worksheet, it is not eligible to apply for exemption using Form 1023-EZ and must instead use the traditional and lengthier Form 1023. The application can only be filed electronically and requires a \$400 "user fee," due at the time the application is submitted. Form 1023-EZ requests information about the applicant's identity (Part I), organizational structure (Part II), specific activities (Part III), and foundation classification (Part IV). Completion of Part V is needed only if the Clinic is seeking reinstatement of its exempt status.

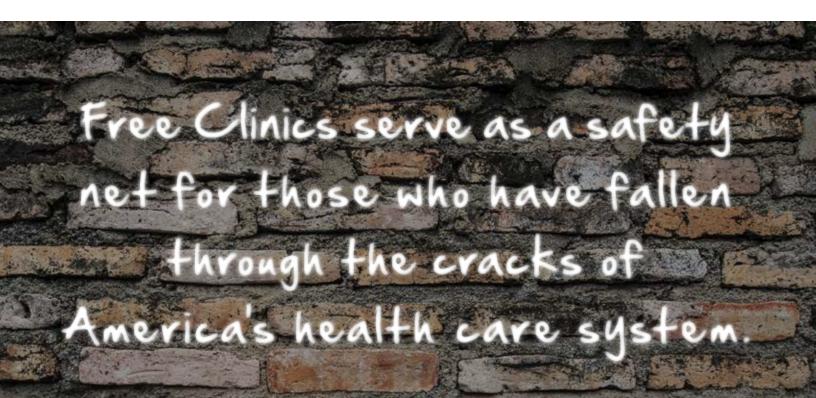
Part I requires, among other things, the full name of the Free Medical Clinic; mailing, website, and contact information; the Clinic's Employee Identification Number; the month in which the Clinic's tax year ends; and information about the Clinic's officers, directors, and/or trustees.

Part II requires the Clinic to identify whether it is a corporation, unincorporated association, or trust, which will impact or determine the necessary organizing documents and date of formation. The applicant must attest that the Clinic's organizing documents limit the Clinic's purpose to one or more of the exempt purposes listed in section 501(c)(3).

Part III requires information about the Clinic's exempt purposes, which must meet the requirements of IRC Section 501(c)(3). In this case, at least one purpose of the Free Medical Clinic would be a "charitable" one, further defined as "relief of the poor, the distressed, or the underprivileged ..." The instructions in Part III also outline the various activities in which an exempt organization must not engage, such as opposing or supporting a political candidate.

Part IV concerns foundation classification. The Free Medical Clinic must identify as either a public charity or a private foundation. According to the IRS, this classification is important as different tax rules apply to the operations of each entity.

Part V requires completion only if the applicant's exempt status automatically revoked under IRC Section 6033(j)(1) for failure to file required annual returns or notices for three consecutive years and the applicant is applying for reinstatement.



Part VI requires the signature of the organization's officer, director, or trustee who has been listed in Part I of the Form 1023-EZ application.

b. Form 1023

The IRS estimates a preparation time of over 100 hours for completion, and IRS approval can range from a couple months to a year, depending on the number of written follow-up questions by the IRS and how quickly the applicant can provide answers. Within several weeks after the application is submitted, the organization should receive a letter from the IRS confirming that the status of its application is "pending." This letter is usually sufficient proof for donors and financial contributors who might require proof of the organization's exempt status.

If tax-exempt status is granted, the IRS will send a "letter of determination" that the organization can use to formally prove its tax-exempt status. The letter provides written assurance about the organization's tax exempt status and its qualification to receive tax-deductible charitable contributions.⁵³ For example, the organization may need to present the letter to foundations when applying for a grant or when applying for state tax-exemption. If the application is submitted within 15 months of incorporation, the determination of tax-exempt status is retroactive to the date of incorporation.

The IRS currently offers three ways in which an organization can complete the lengthier Form 1023:54

- Interactive Form 1023—The Interactive Form is viewed online but cannot be filed online. The form must be printed out and mailed to the IRS. The main advantage, however, of this form is that it provides pop-up information and automatically takes the user to other locations on the form where supplemental information is required.
- Standard PDF Form 1023—The Standard PDF Form has a few helpful features that are not in the Accessible Form 1023.
- ♦ Accessible Form 1023—The Accessible Form is a simple PDF that the user must print out and mail to the IRS. It does not contain any of the helpful pop-up features or links provided by the Interactive or Standard Forms.

2. Schedule A

Providing thorough and accurate information to illustrate the organization's compliance with Section 501(c)(3) requirements throughout the application is the key to a successful application. Schedule A of Form 1023 contains eleven parts that the applicant must complete to be considered by the IRS for tax exemption. The following section provides additional information on select Parts of the application.

Part III is significant because it requires that the entity's organizing document state a purpose that fits within the accepted norms of Section 501(c)(3) organizations. According to the IRS, "this requirement may be met if the purposes stated in the organizing document are limited by reference to section 501(c)(3)." Part III also requires that the organizing document indicate how its assets will be distributed upon dissolution to comply with the requirement that they be distributed for an exempt purpose described in section 501(c)(3), or to the federal government or to a state or local government for a public purpose.⁵⁵

Part IV is widely considered the most important section of the application. It requests a description of the organization, including the organization's purpose and past, present, and anticipated activities. It is crucial to emphasize in this section that the organization was formed for charitable purposes and the organization's adherence to the IRC's standards relating to tax-exempt organizations. The IRS advises that the narrative description reference information in other parts of the application, such as activities and services, and include answers to the following questions:

- What is the activity?
- Who conducts the activity?
- When is the activity conducted?
- Where is the activity conducted?
- A How does the activity further the organization's exempt purposes?
- What percentage of the organization's total time is allocated to the activity?
- ♦ How is the activity funded?⁵⁶

Part V requests information about each board member, director, officer, trustee, employee, and independent contractor. The IRS requires that each person's compensation be reasonable and comparable to similarly skilled individuals working in similar geographic markets. To help demonstrate compliance with this standard, the organization must specifically "list the name, title, mailing address and total compensation for officers, directors and trustees; employees receiving more than \$50,000 annually; and independent contractors receiving more than \$50,000 annually." Compensation is defined as "all income including salary, wages, deferred compensation, retirement benefits, fringe benefits, educational benefits, low interest loans, payment of personal expenses, and bonuses." ⁵⁷

The organization should have conflict of interests policies and procedures in place prior to commencing the application process as Part V requires disclosure of transactions that may pose a conflict of interests for the organization. The organization also must disclose in this section information about family and business relationships and transactions that could generate a private benefit, which is prohibited for tax-exempt organizations. This Part will also require information about the qualifications of the volunteer officers, directors, and trustees.

Part VI requires an explanation of how the organization will distribute its services to the community. Specifically, this Part is concerned with whether the organization is limiting its programs to certain groups and whether "individuals related to key individuals are eligible to receive benefits from the organization." The purpose of Part VI is to ensure that the organization applying for exemption operates to benefit the public rather than a private entity or individual.⁵⁸

Part VIII requires a description of the organization's activities. Tax-exempt organizations are prohibited from engaging in activities that will result in private inurement for others or activities that involve excess benefit transactions and political activity. In addition, the IRS will more closely scrutinize activities in which a tax-exempt organization can engage but with limitation, such as lobbying, commercial fundraising, and joint ventures with for-profit entities. Only actual and planned fundraising activities should be described in this section. Generally, the contemplated activities of a Free Medical Clinic will not fall into any of these prohibited or limited activities. Question 20 asks whether the organization's "main function" is to provide "hospital or medical care." Mark "Yes" and complete Schedule C. Part VIII also asks about the organization's connection with other organizations so that the IRS can develop "information about separately established organizations that have (or plan to have) a relationship involving sharing or coordinating finances, employees or activities." If the organization has no current or planned relationships with other organizations, it would simply state that no such relationship exists or is intended to be formed. Organizations

Part IX requires the applicant to provide financial data so that the IRS can make the determination of whether the organization is (or will be) publicly supported (i.e., not a private foundation). The organization must provide narrative and financial descriptions of past, current, and future activities and purposes. 61 The Statement of Revenue and Expenses "requires the organization to provide actual or projected financial information (e.g., budget) for three or four years (depending on how many years it has existed)." A balance sheet for the organization's recent tax year is required by the IRS and should be "a snapshot of assets, liabilities and fund balances (net assets) on a particular date. If an organization has not completed a tax year, it should provide a statement of actual assets, liabilities and fund balances (net assets) based on its most current information."62 The tax years for which an organization must provide financial information depends on how many tax years (annual accounting period) an applicant has completed since formation. If an organization has been in existence for less than 5 years, the IRS requires that it must complete the schedule in Part IX for each year in existence and provide projections of likely revenues and expenses based on a reasonable and good faith estimate of future finances for a total of three years of financial information if it has not completed one tax year, or four years of financial information if it has completed one tax year. If in existence for five years or more, it must complete the schedule for the most recent five tax years. It will need to provide a separate statement that includes information about the most recent five years because the data table in Part IX does not provide for the fifth year.⁶³

Finally, Part X requests that the organization specify whether it is a private foundation or a public charity. In this case, the organization (i.e., Free Medical Clinic) will likely be a public charity, which has a more favorable tax status.

G. Tax-Exempt Status Under State Law

Most Free Medical Clinics are tax-exempt under IRC Section 501(c)(3). Clarifying key distinctions and definitions, however, is important to better understand how an entity can qualify for and benefit from tax exemption. The term "nonprofit" is not synonymous with "tax-exempt." "Nonprofit" is a concept connected to state organizational law in which the nonprofit entity is formed by incorporating under a state nonprofit corporations act or by forming a common-law charitable trust or a charitable unincorporated association. The main requirement for obtaining nonprofit status under state law is the non-distribution constraint, which prohibits a nonprofit from having equity owners who are entitled to receive distributions of the nonprofit entity's net revenues.⁶⁴

Nonprofit status is a requirement of tax exemption, but is not a sufficient standalone condition for exemption. ⁶⁵ Rather, tax exemptions are conferred by state and federal tax law, not by state organizational law. In most cases, exemption involves multiple levels of separate taxes imposed by at least multiple taxing jurisdictions: (1) the federal income tax, (2) the



state income tax, (3) the state property tax, and (4) the state sales/use tax.⁶⁶ Exemption from federal income tax and state property tax is essential to understanding tax exemption policies in health care. In short, states can and often do impose different and more rigorous exemption criteria than are currently imposed by federal law.⁶⁷

At the federal level, exemption depends on meeting the standards of the relevant subsection in Section 501.68 Health care providers often qualify for federal income tax exemption under Section 501(c)(3) as "charitable" organizations.69 In this area, it is common for state income tax exemption rules to mirror federal income tax exemption laws under the Code. For example, Illinois' statute70 bases state income tax exemption on federal exempt status under IRC Section 501.71 While state property tax and sales tax exemption laws tend to be consistent with federal income tax exemptions, some states may have their own exemption standards that are more specific and stringent. In addition, an organization that qualifies for federal tax exemption usually will receive state income tax exemption as well, but may not automatically receive state property tax exemption or sales tax exemption. In many states, property tax exemptions are authorized by the state constitution and implemented via enabling legislation passed by the state legislature.72 It is essential to check the state tax agency where a Free Medical Clinic has registered to do business given the significant variations in state laws governing property and sales/use tax exemptions.

Free Clinics remain one of the only health care providers in the country to provide essential health care sevices, regardless of the patient's ability to pay.

CHAPTER 3: State Laws on Licensure and Other Authorizations

A. Licensure of the Free Medical Clinic

The licensing requirements for opening and operating a Free Medical Clinic are state specific. Depending on the state, structure, and the medical services provided, the Free Medical Clinic may, in some cases, need only verify and credential that its medical providers are properly licensed to practice in the state. For instance, Pennsylvania does not require special licensing but allows volunteer medical provider licensure to retired health care providers with board-issued licenses in good standing or to those who are not retired but are otherwise not required to maintain professional liability insurance. These licensed volunteer medical providers are allowed to provide primary health care services and treat patients within his or her scope of practice and in accordance with his or her medical license as a physician, nurse or other medical care provider without pay.⁷³

1. Student-run Clinics

Student-run Free Medical Clinics are operated in conjunction with medical schools where the medical students provide services under the supervision of a licensed physician and other faculty members. Student-run Clinics are also operated in partnership with nursing schools where care is provided by graduate-level nursing students under the supervision of licensed nursing practitioners. Both types of student-run Clinics serve the dual purposes of training the students and offering free or reduced care. Although these Clinics are operated within medical schools, the same licensure requirements usually apply with respect to licensing the Clinic itself.

2. Nurse Practitioner-led Clinics

Some Free Medical Clinics are operated by nurse practitioners (NPs) under a full practice, reduced practice or restricted practice model. In most states and the District of Columbia, NPs may provide medical care completely independent of physicians, effectively allowing them to operate in a fashion similar to primary care physicians. This independence is referred to as "full practice" and allows NPs to "evaluate patients, diagnose, order and interpret diagnostic tests, initiate and manage treatments—including prescribe medications—under the exclusive licensure authority of the state board of nursing." In a minority of "reduced practice" states such as Indiana, an NP's ability to provide patient care is limited and requires a regulated collaborative agreement with an outside health discipline, such as a physician, hospital or physician health network. State regulations and collaborative agreements often require a physician to review a small number of patient charts per month but in most states, the physician need not be in the same location when patients are being treated

by nurse practitioners. An even smaller minority of states regulate nurse practitioners' under a "restricted" practice model, which requires supervision, delegation or team-management by an outside health discipline.⁷⁴ As one can see, the statutory requirements, the actual collaborative agreements entered into, and limitations on nurse practitioners in reduced and restricted practice states can vary greatly.

Some states, such as Wisconsin, leave the scope of collaborative agreements open-ended. According to Wisconsin's Nurse Practice Act, "[t]he collaborative relationship is a process in which an advanced practice nurse prescriber is working with a physician, in each other's presence when necessary, to deliver health care services within the scope of the practitioner's professional expertise. The advanced practice nurse prescriber and the physician must document this relationship." Missouri, on the other hand, is a restricted practice state that requires collaborating physicians to review on a biweekly basis 10% of nurse practitioner care services and 20% of the prescriptions they write. Alabama, another restricted practice state, requires the collaborating physician be on-site for at least 10% of the NP's scheduled hours. By contrast, Texas requires that an NP practice within 75 miles of the delegating physician's residence or primary practice site."

B. Licensure of Medical Volunteers

Medical volunteers may include physicians, nurses, physician assistants, mental health professionals, pharmacists, dentists, social workers, and pastoral workers, all of whom require special licenses to practice in accordance with their state's statutes, regulations, and medical board determinations, if applicable.

1. Physicians

In order to obtain a physician's license and practice medicine, an individual must have a medical degree from an accredited, state board-approved medical school and postgraduate training, which requires a minimum three-year residency. Formal education (i.e., four years of medical school plus residency) can take several years, depending on the medical specialty. For example, a family practice residency usually requires three years of training, while a surgical residency (e.g., general, orthopedic, neurosurgery) typically requires an additional five to eight years or longer.

Prior to obtaining a license to practice medicine, the physician must pass the United States Medical Licensing Examinations (USMLE) or the Comprehensive Osteopathic Licensing Examination-USA (COMLEX-USA).⁷⁸ Some states also allow other types of medical licensing exams, such as the National Board of Medical Examiners (NBME), the National Board of Osteopathic Medical Examiners (NBOME), the Federation Licensing Examination (FLEX), or other state-structured exams.⁷⁹



States set physician license renewal requirements, which generally must be met annually or biennially. States also require physicians to complete a certain number of continuing medical education (CME) hours.⁸⁰ Many states allow medical students who are not yet licensed to assist as volunteers in Free Medical Clinics when appropriately supervised by licensed physicians.

2. Nurses (NPs, LPNs, and RNs)

States govern the licensure of NPs, licensed practical nurses (LPNs) and registered nurses (RNs). Each state's Nurse Practice Act sets forth requirements for each of the nurse classifications. The main difference between each classification is the level of education required. For example, one can generally complete an LPN program in one year or less, while most RN programs require two years of education for an associate's degree and three to four years for a bachelor's degree. While all nurses must pass a state or national examination, such as the National Council of State Boards of Nursing National Council Licensure Examination (NCLEX), the exams typically differ for LPNs and RNs. For instance, the NCLEX-PN is specific to LPNs and the NCLEX-RN is required for RNs. As for NPs, all states require them to have a bachelor's degree in nursing, a Registered Nurse (RN) license, and advanced training beyond undergraduate training.

Responsibilities also differ among the nurse classifications. In many states, LPNs have more administrative responsibilities than RNs and are not able to perform intravenous duties or must complete additional coursework and certification. Nurse practitioners can prescribe medicine in many states with some limitations.⁸⁵ On the other hand, some states require NPs to collaborate with a physician for a certain number of years prior to practicing independently. In other states, NPs must provide services as delegated or supervised by a physician.

3. Mental Health Professionals

Many mental health professionals, such as psychologists, psychiatrists, and counselors, require licensure under state law. A bachelor's degree and a doctoral degree are required for psychologists, in addition to corresponding continuing education requirements and various licensure exams depending on the psychologist's area of specialization. Psychologists and psychiatrists differ in that that psychiatrists are medical doctors and can prescribe psychiatric drugs or other medications. States generally require a bachelor's degree, some graduate education, a certain number of Clinic hours within a counseling setting, and applicable education requirements to obtain a license for counseling. Licensure requirements can be less defined, however, in other states.

During 2012-2014,
the nation's 1,200 Free Clinics
saw a 40% increase
in patient demand,
despite the full implementation
of the Affordable Care Act.

4. Social Workers and Clergy

Each state regulates and establishes the standards for licensure of clergy and social workers. For example, a social worker's license typically requires a bachelor's degree, master's degree in social work and two years of direct clinical social work experience. Some states, such as Virginia, North Dakota, and South Carolina, may require up to four years of supervised experience. Many states also require social workers to continue their education through courses relevant to their specialty for the purpose of maintaining licensure.

Licensing requirements for clergy, sometimes referred to as spiritual caregivers or pastoral counselors, also will vary by state. In addition, the label "clergy" can emcompass several different types of licensed caregivers or counselors, such as the certified clinical pastoral therapist (CCPT), licensed professional counselor (LPC), licensed mental health counselor (LMHC), or licensed marriage and family therapist (LMFT). The American Association of Pastoral Counselors provides a state directory of what types of licensing are available or required by each state, as well as other helpful information (visit www.aapc.org).

5. Physician Assistants

Physician assistants (PAs) provide services under the supervision of a physician who is legally responsible for the actions undertaken by the PA in the course of providing medical care to patients. In most states, PAs have also been delegated with the authority, by their supervising physicians, to prescribe medications, but some states may require that the PA practice for a certain number of years before having the authority to write prescriptions.

All states require that PAs be licensed. A physician assistant must have at minimum a bachelor's degree in physician assistant studies. Many states also require a graduate degree that has been accredited by a national organization, such as the American Academy of Physician Assistants. Once the individual has fulfilled the educational requirements for his or her state, most of those states will also require passage of a national examination before the individual can begin practicing as a PA. Like other health care professionals, PAs are often required to complete continuing education courses to maintain licensure.

6. Pharmacists

A pharmacy license requires either two years of non-degree laboratory science preparation or a bachelor's degree in laboratory science and successful completion of a four year Doctor of Pharmacy (Pharm.D) program from a pharmacy school that has been accredited by the Accreditation Council for Pharmacy Education (ACPE). A pharmacist can specialize by receiving further education in a specialty area, such as pediatric, oncology, or psychiatric pharmacy to name a few. After fulfilling the educational requirements, the individual must

pass the North American Pharmacist Licensure Examination to practice pharmacy and comply with continuing education requirements to maintain his or her licensure.

7. Dentists

In nearly all states, a dentist must have a bachelor's degree and a graduate doctoral degree in dentistry from a dentistry program that has been accredited by the American Dental Association Commission on Dental Accreditation. A dentist can pursue additional training to specialize in an area such as orthodontics. To maintain licensure, all dentists must fulfill continuing education requirements, which are established by each state's dental boards.⁸⁸

8. Specialized Services

If a Free Medical Clinic wishes to offer specialized services, such as behavioral health, some states may allow the Clinic to operate without additional licenses and within the scope allowed by the medical provider's license. Other states may, however, require special state licensures. Because state laws vary on this matter, Clinic organizers should check their states' statutory and regulatory requirements if they want to provide specialized services outside the scope of primary care.

C. Credentialing and Privileging

Credentialing is the process of evaluating a physician's qualification and practice history, which is conducted through primary and secondary source verification. Secondary source verification is simpler, requiring, for example, an original credential such as government issued identification. This section will therefore focus on primary source verification. Privileging is the process of authorizing the provider's specific scope and content of patient care services, and can be completed during the primary source verification phase of the credentialing process.

Primary source verification—which can be performed by the Free Medical Clinic internally or by a Credentialing Verification Organization (CVO)—confirms "an individual health care practitioner's reported qualification by the original source or an approved agent." If conducting the verification internally, clinic organizers should contact the educational institutions listed in the health care practitioner's curriculum vitae and verify that he or she graduated from said medical (or other applicable) school. Clinic organizers can also verify a physician's credentials through the Education Commission for Foreign Medical Graduates (ECFMG) if the physician attended a foreign medical school; the American Board of Medical Specialties (ABMS); the American Osteopathic Association (AOA) Physician Database; or the American Medical Association (AMA) Masterfile.⁸⁹ If the Clinic chooses to outsource its primary source verification obligations to a CVO, it should maintain complete and accurate information about the

Without the care provided by over 100,000 medical experts who volunteer their services at Free Clinics working families may Hottinable to secure the health care they need.

outcome of all the primary source verifications, including the agreement used to enter into the arrangement with the CVO. Such documentation will be important if a Free Medical Clinic is audited by any federal or state licensing or auditing organization. Once the credentialing process is complete, all information gathered for a particular provider should be on file for inspection when necessary. The credentialing process should be conducted every two years to ensure information provided by the health care provider remains accurate and current.⁹⁰

As for the privileging process, a review of the health care provider's ability to perform the services that he or she is requesting to perform will likely be evident from his or her education and training. If such information is not evident, the Free Medical Clinic can request information from other health care entities at which the health care provider already holds privileges. If experience is lacking or sufficient information cannot be obtained, one-on-one proctoring or review of the individual by a more experienced health care professional who already holds similar privileges can help ascertain the individual's qualifications. The Free Medical Clinic should also confirm that the health care provider is physically able to perform the specific services for the relevant privilege(s), which can be done by requesting a statement from a hospital or other entity in which the individual already holds the same privilege(s). Ultimately, the Free Medical Clinic's board of directors must approve, in writing, the privileges requested by the health care professional. The approval can be granted following a recommendation from the medical director, chief of staff, or the medical staff as a whole.⁹¹

In addition to conducting primary and secondary source verifications, clinic organizers should check the HHS OIG's List of Excluded Individuals and Entities (LEIE)⁹² and the National Practitioner Data Bank (NPDB).⁹³ The LEIE provides information to the health care industry, patients, and the public about individuals and entities that are currently excluded from participating in any of the federal health care programs, including Medicare and Medicaid. The effect of an exclusion is significant: no payment will be made by any federal health care program for any items or services furnished, ordered or prescribed by an excluded individual or entity. Free Medical Clinics should therefore take care to ensure that none of its health care providers are on the LEIE. The NPDB was created pursuant the Health Care Quality Improvement Act of 1986, which provides immunity protection to certain entities conducting professional review activities for health care providers. The NPDB warehouses information from various reporting entities about adverse actions initiated against health care providers arising out of their professional competence or conduct.⁹⁴ The results of an NPDB report can help determine whether or not the Free Medical Clinic decides to credential and privilege a particular health care provider.

D. Deemed Status Under the Federal Tort Claims Act

On March 22, 2011, the United States Department of Health and Human Services, Health Resources and Services Administration (HRSA) issued Policy Information Notice 2011-02 (PIN), outlining the requirements for credentialing and privileging for Free Medical Clinics seeking deemed status for its volunteers under the Federal Tort Claims Act (FTCA). If Clinic organizers and operators want their volunteers and employees deemed as Public Health Service (PHS) employees for FTCA coverage, the sponsoring Free Medical Clinic must provide assurances that all credentialing and privileging requirements have been met. Further, the Free Clinics FTCA Program divides licensed health care professionals eligible for FTCA coverage into two categories: (1) licensed independent practitioners (LIPs) and (2) other licensed practitioners.

Licensed individual practitioners, such as physicians, dentists, and some advanced practice clinicians, are permitted by law to provide services without direction or supervision. Other licensed or certified practitioners are not permitted by law to provide services without direction or supervision, which includes laboratory technicians, social workers, medical assistants, licensed practical nurses, and dental hygienists.⁹⁵



The Free Clinics FTCA Program requires different credentialing and privileging requirements depending on whether the individual is a LIP or other licensed or certified health care practitioner. The sponsoring Free Medical Clinic must complete the credentialing process for eligible LIPs, which includes the following:

- Primary source verification of current licensure and relevant education, training, or experience;
- Secondary source verification of (a) identification (via a government issued picture ID); (b) Drug Enforcement Administration registration, if applicable; (c) hospital admitting privileges, if applicable; (d) immunization and tuberculosis skin test results; (e) life support training, if applicable; Additional verification by querying the NPDB or requiring the LIP to provide the results of a self-query; and
- A determination of the practitioner's health fitness or ability to perform the requested privileges, which can be determined by a statement from the individual that is confirmed either by the director of a training program, chief of staff/service of a hospital where the individual has privileges, or a licensed physician designated by the organization.⁹⁶

Initial privileging of LIPs involves assessing the practitioner's competence in the specific scope of service he or she will provide. Such assessment can be conducted through primary source verification of a LIP's certification from an educational institution, documented review of the individual's competence by a supervising Clinician who has privileges in a particular procedure, or director proctoring of the LIP in a particular procedure. The governing board of a Free Medical Clinic should certify in writing its approval that the LIP meets credentialing and privileging requirements based on the recommendation of the Clinic's medical director and executive director. Alternatively, the task of primary source verification can be delegated to an appropriate individual or CVO to make this determination based on approved policies and procedures. Free Medical Clinics should reassess their LIPs' credentials and privileges at least every two years and have an appeal process that LIPs can pursue if the Clinic decides to discontinue or deny Clinic privileges.⁹⁷

For other licensed or certified health care practitioners, the initial credentialing should include (1) primary source verification of current licensure, registration or certification; (2) secondary source verification of education and training; identification (via a government issued picture ID); (3) Drug Enforcement Administration registration, if applicable; (4) hospital admitting privileges, if applicable; (5) immunization and PPD status; (6) life support training, if applicable; and (7) results of an NPDB query or self-query, if applicable. Similar to the privileging process for LIPs, the initial

privileging of other licensed or certified health practitioners involves assessing the individual's competence in the specific scope of services that he or she is to provide at the Clinic. The assessment can be done through an orientation process during which a supervisor evaluates the practitioner's qualifications and competence. Reassessment of the credentials and privileges of other licensed or certified practitioners should also be conducted at least every two years. 98

E. Pharmacy Distribution Licensure

Free Medical Clinics that plan on distributing drugs or have an on-site pharmacy must comply with both federal and state licensing requirements. These requirements regulate who can access and distribute drugs and how and where drugs must be stored on-site. Failure to comply can result in suspension or revocation of the Clinic's and/or health care provider's drug license and may also include other penalties, such as fines or imprisonment.⁹⁹

1. Federal and State Regulations

State laws regarding prescription drug-related licenses must incorporate all applicable federal regulations such as those set forth by the Food and Drug Administration (FDA).¹⁰⁰ In accordance with federal policy, states have implemented various licensing regimes for pharmacists. In most states, such licenses are issued by the state's Board of Pharmacy and require periodic renewal. Clinic operators should check their state's laws as the definition and requirements for pharmacists may vary.

2. Narcotics

If a Free Medical Clinic plans to distribute narcotics or controlled substances, both the Clinic and the health care provider must comply with additional federal and state requirements regarding controlled substances.¹⁰¹ The Drug Enforcement Agency (DEA) requires all "practitioners" to have a valid state medical and/or controlled substance license and to register with the agency, which can be done online. DEA registration grants the practitioner (including physicians, dentists, pharmacies, and hospitals) authority to handle controlled substances. The Clinic also must meet state and federal drug security requirements with respect to handling and dispensing narcotics and maintain an alarm system for the pharmacy area to properly secure narcotics.

The DEA has the authority to deny, suspend, or revoke a DEA registration if the registrant has materially falsified any application filed; been convicted of a felony relating to a controlled substance; had a state license revoked or denied; rendered any act that would be inconsistent with the public interest; or been excluded from participation in a Medicaid or Medicare program.¹⁰²

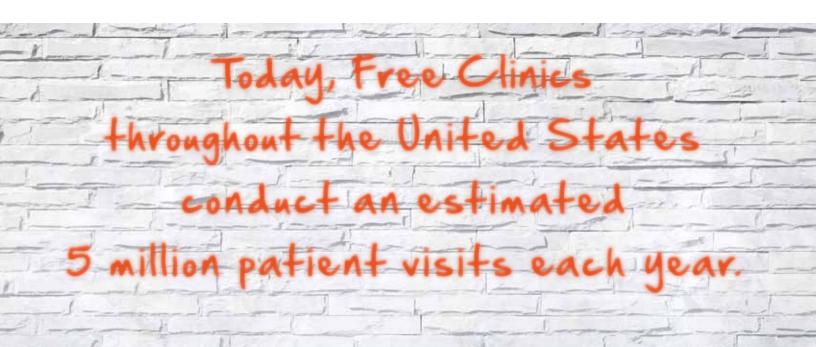
F. Other State Specific Requirements

Other state-specific requirements may apply if a Free Medical Clinic provides imaging services such as x-rays. If so, the Clinic should ensure that its employees are appropriately licensed to operate any imaging equipment the Clinic has. In 1981, Congress adopted the Consumer-Patient Radiation Health and Safety Act (CPRHS),¹⁰³ which directed the Secretary of Health and Human Services to develop standards for state certification and licensure of personnel who administer radiology in medical and dental settings. Adoption of these standards was discretionary rather than mandatory, resulting in forty-three states developing any regulatory guidelines for radiologic personnel. The standards are state specific and vary dramatically from state to state.¹⁰⁴ Radiation-emitting machine (e.g., X-ray and CT machines) should also be appropriately registered with applicable state agencies. If the Clinic is unsure about whether a particular machine should be registered, it should inquire with the applicable state agency to ensure compliance.¹⁰⁵

CHAPTER 4: Limiting Liability

A. The Good Samaritan and an Analysis of Existing Laws

A Good Samaritan (GS) statutes offer an available affirmative defense and protects persons against civil liability for injuries or even death due to negligent actions or omissions while rendering health care assistance, usually under emergency circumstances.¹⁰⁶ All 50 states and the District of Columbia have enacted at least some form of Good Samaritan legislation to encourage individuals to render medical assistance in certain situations by limiting their civil liability to damages stemming from egregious acts. Some states have a single statute, while others address the issue through a number of different statutes. GS statutes



throughout the country share some common elements, but the scope of the protection they provide can vary significantly. It is important, therefore, that Clinic organizers ascertain the scope of protection provided by their state's relevant GS statute, especially as the statute may offer a sufficient level of civil liability immunity to practitioners that may offer an alternative to professional liability insurance. While a majority of jurisdictions offer access to some form of liability coverage under a GS statute, volunteers in other jurisdictions may find they have to purchase their own liability policies or have their employers extend coverage.¹⁰⁷

Before granting that qualified immunity, GS statutes impose preconditions that address (1) the persons covered by the statute;¹⁰⁸ (2) the circumstances giving rise to the necessary assistance provided;¹⁰⁹ (3) the standard of care imposed on individuals providing the assistance or conduct for which immunity is voided;¹¹⁰ and (4) whether compensation was exchanged or expected in return for the assistance.¹¹¹ The individual who rendered assistance has the burden of proving the relevant elements. Current GS statutes offer varying degrees of legal protection, but this section focuses on their most common elements and those applicable to Free Medical Clinics.¹¹²

1. Persons Covered

The majority of states' GS statutes do not restrict the civil liability protections to limited sets of individuals (e.g., licensed health care professionals), and many require that protected health care practitioners not act outside the scope of the medical specialty for which they are licensed. Some states do, however, provide immunity only to health care practitioners who are duly licensed within their jurisdictions or to those who meet specific criteria (e.g., public school employees). Still, others protect individuals who have "medical training" but do not require an in-state license. A small number of states provide immunity to physicians or nurses only, but others do not require an active license within that jurisdiction or may even allow immunity for retired physicians. At least one state's GS statute requires that the operator of the Free Medical Clinic "use due care in the selection of volunteer medical or health care providers." GS statutes vary from state to state, so it is important for Clinic organizers to understand whom their state's statute protects.

2. Circumstances

The circumstances, such as time and location, in which a Good Samaritan provides assistance will determine whether immunity attaches. All states provide protection for health care assistance rendered at the scene of an emergency, but some statutes may provide more flexible definitions of an "emergency" than others. For instance, a few GS statutes allow immunity for emergency care rendered inside a hospital, but the District of Columbia limits the site of emergency care to locations outside a hospital. This means that assistance provided by health care personnel inside a hospital emergency department in the District of Columbia would not qualify for statutory protection. ¹¹⁶

The Free Medical Clinic setting is unique under GS statutory analysis because it requires states to extend civil liability protections for health care services rendered in non-emergency situations. Some states expressly address care provided at Free Medical Clinics. For example, a Maryland statute provides protection to a health care provider or physician who renders health care services . . . at or through a charitable organization. States that have Clinic-specific GS statutes generally define the type of facility and nature of services provided that would qualify for protection. For instance, Illinois defines a Free Medical Clinic as an organized community based program providing medical care without charge to individuals unable to pay for it, at which the care provided does not include the use of general anesthesia or require an overnight stay in a health-care facility.

Still, other states have extended their application beyond the state law definition of "Free Medical Clinic." Other states have made clear that health care practitioners who treat a patient following a referral from a Free Medical Clinic may rely on GS statutory protection. In contrast, Idaho's GS statute expressly states that immunity ends once the patient is delivered to the next site of care.¹²⁰

3. Standard of Care

Health care providers have a duty to act reasonably while treating their patients. The majority of GS statutes require that, at minimum, medical aid be provided without gross negligence. Intentional bad acts void the immunity. Virginia's GS statute defines gross negligence as the "degree of negligence which shows indifference to others as constitutes an utter disregard of prudence amounting to a complete neglect of the safety of [another]. It must be such a degree of negligence as would shock fair minded men although something less than willful recklessness." The standard in some GS statutes require that the medical assistance provided be reasonable and prudent given the circumstances, without referring to the concept of gross negligence. Regardless, actions or omissions constituting reckless or willful misconduct generally do not receive protection under GS statutes.

4. Required Conduct

Most GS statutes require that medical aid be provided in good faith and/or gratuitously without charge.¹²³ Good faith is not, however, a universal requirement in GS statutes.¹²⁴ The Free Medical Clinic should, therefore, review the case law in its jurisdiction to learn how courts will apply the good faith definition to its operations.

In addition, many states require that the care be rendered gratuitously and without expectation of remuneration. Accordingly, GS statutory immunity would be voided if the health care provider at a Free Medical Clinic received compensation from the patient. This does not, however, preclude health care providers from receiving normal compensation or reimburse-



ment from the Clinic for the reasonable expenses of providing care. Also, some states do not prevent a Free Medical Clinic "from accepting voluntary contributions for medical services provided to a patient who has acknowledged his or her ability and willingness to pay a portion of the value of the medical services provided." However, some states like Illinois may require that "[a]ny voluntary contribution collected for providing care at a Free Medical Clinic shall be used only to pay overhead expenses of operating the Clinic. No portion of any moneys collected shall be used to provide a fee or other compensation."

Some GS statutes focus on the patient's ability to pay as well as the health care provider's expectation of compensation for the care. In Ohio, "health care workers who are volunteers are not liable in damages . . . in a tort or other civil action . . . to an *indigent and uninsured* person" (emphasis added). The Ohio statute defines an "[i]ndigent and uninsured person" as one whose "income is not greater than two hundred per cent of the current poverty line" and is "not eligible for the [M]edicaid program or any other governmental health care program." Thus, Free Medical Clinics located in states that have GS laws similar to Ohio's must decide whether to (1) accept only patients who meet these eligibility requirements to ensure the Clinic may rely on GS statutory protections or (2) treat all needy patients, regardless of the criteria and forgo protection under Good Samaritan legislation. Other states may require that the Free Medical Clinic provide notice of its responsibility to provide care gratuitously and of that fact that it is entitled to civil immunity for that care under the law.

5. Covered Procedures

Services provided by a Free Medical Clinic can include the basics, such as school physicals and blood pressure checks, or specialty services in dermatology, obstetrics-gynecology, dental services, or even substance abuse and psychological counseling. Some GS statutes expressly exclude certain procedures from protection. For example, Ohio's GS statute does not provide protection for (1) procedures not typically performed in an office setting; (2) procedures beyond the practitioner's scope of practice or competence; (3) actions that are outside the practitioner's scope of authority; (4) procedures requiring deep sedation or general anesthesia; or (5) delivery of a baby or abortion unless necessary to preserve life. Thus, a Free Medical Clinic must determine the scope of services protected under the relevant state law and plan accordingly so that it has insurance for services rendered outside the scope of the statutory protection.

B. The Federal Tort Claims Act

1. Liability Coverage Under the FTCA

Under the Federal Tort Claims Act (FTCA),¹³⁰ plaintiffs cannot sue federal governments, agencies, and their employees—a concept commonly known as "sovereign immunity"—without the government's consent to be sued. The FTCA, however, provides limited waivers of fed-

eral sovereign immunity. Under the FTCA, plaintiffs may directly sue the federal government for injuries or death caused by an employee's negligent or wrongful acts or omissions while acting within the scope of his or her government employment, subject to specific limitations.

Congress determined it was important to let the federal government's sovereign immunity pass through to Free Medical Clinics so that more of a Clinic's grant funds could be used for providing actual health care services rather than buying malpractice insurance, for which premiums were high in proportion to the claims actually paid out.¹³¹

Medical malpractice liability coverage is available for individuals working at Free Medical Clinics under the FTCA. Enactment of Section 194 of the Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104-191), which added a new subsection to Section 224 of the Public Health Service Act (PHSA) (42 U.S.C. §233(o)), also afforded coverage to volunteer health professionals of Free Medical Clinics. Coverage was further extended to cover eligible board members, officers, employees, and contractors of Free Medical Clinics through passage of the ACA. Thus, the federal government, through the Bureau of Primary Health Care (BPHC) in the U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), assumes all financial responsibility for the costs of judgments awarded in favor of plaintiffs for successful tort claims using a program commonly referred to as the Health Center FTCA Medical Malpractice Program. BPHC also annually collects data on sponsoring Free Medical Clinics, including the number of deemed health care professionals at the Clinic, number of patients seen, and number of visits per year. The reporting forms can be found on the HRSA website.

A Clinic's health professionals, board members, officers, employees, and contractors are not automatically covered by FTCA. The Clinic must submit an annual application for "deeming" on behalf of the individuals to BPHC, which administers the program. Individuals who meet all statutory and program requirements are considered "deemed" Public Health Service employees upon approval by the Secretary for Health and Human Services. A deemed PHS employee has immunity from medical malpractice lawsuits and related civil actions resulting from performing qualifying health services on behalf of the sponsoring Free Medical Clinic. Persons alleging acts of medical malpractice by deemed PHS employees must file their claims against the United States under the FTCA. As of May 16, 2013, HRSA requires that all applications be submitted using its web-based Electronic Handbook system.¹³⁵

FTCA protection also requires that deemed individuals meet other conditions such as (1) being sponsored by the Free Medical Clinic; (2) securing licensure or certification pursuant applicable laws; (3) being credentialed and privileged according to the Free Clinics FCTA Program; (4)

providing qualifying health services without compensation in the form of salary, fees, or third-party payments (although they may receive repayment from the Clinic for reasonable expenses incurred); (5) providing their services through a Free Medical Clinic or offsite program or event sponsored by the Clinic; and (6) providing patients with written notification, prior to providing services, that the volunteer or employee's legal liability is limited pursuant to PHSA. Finally, Free Medical Clinics must apply to the U.S. Department of Health and Human Services to have each health care professional deemed a "free clinic health professional." ¹³⁶

The FTCA further requires that the Free Medical Clinic not receive "any compensation for the service from the individual or from any third-party payer" for a health service to be covered with medical malpractice insurance through the Free Clinics FTCA Program.¹³⁷ Even if a Clinic charges for health services based on a sliding scale and later elects not to pursue the charge, FTCA coverage is not available unless the Clinic can show the charge was an administrative error or that the decision to not pursue payment was not for the purposes of gaining FTCA coverage.¹³⁸

2. Deemed Employees

Deemed PHS employees have medical malpractice coverage through the Free Clinics FTCA Program for negligent acts or omissions that:



"(1) arise from services required or authorized to be provided under Title XIX of the Social Security Act, (2) arise from the provision of medical, dental, or related services at a free clinic site or through offsite programs or events carried out by the free clinic, (3) occur during the effective deeming period after a FTCA deeming application submitted by the free clinic on behalf of its eligible individuals ... is approved, and (4) arise from services provided at a free clinic or through offsite programs or events carried out by the free clinic in which no charge was imposed on a patient." ¹³⁹

Also covered are offsite programs and events, including health fairs or similar events where a Free Medical Clinic provides health screenings or educational activities. Clinic organizers should seek clarification regarding FTCA coverage from the Free Clinics FTCA Program.

3. Program Requirements

Free Medical Clinics that sponsor individuals for FTCA coverage must provide HRSA with a copy of the Clinic's quality improvement/quality assurance plan, which should outline the clinic's plan to mitigate risk, improve patient quality, and address the Clinic's credentialing and privileging processes. This plan should be signed, approved, and reviewed at least every three years by the Clinic's board of directors. HRSA also requires that Free Medical Clinics disclose medical malpractice claims from the past ten years for each individual seeking FTCA coverage. In their annual applications to HRSA for FTCA coverage, Clinics should include an explanation of any medical malpractice suit and any risk management actions taken by the Clinic or the individual to prevent similar complaints in the future.

4. Qualifying Health Services

The FTCA's protections may still apply if a Free Medical Clinic is operated by a nonprofit private entity. The protection is limited to harm from "qualifying health services" performed by licensed or certified health care practitioners, who are called "free Clinic health professionals." A qualifying health service is any act of "medical assistance required or authorized to be provided" under the Medicaid program as described in Title XIX of the Social Security Act, regardless of the state where the medical assistance occurred actually provides reimbursement for that health service under the terms of its state Medicaid plan submitted to the federal government. The FTCA protections apply to qualifying health services rendered at the Clinic's location and to qualifying health services provided through "offsite programs or events carried out by the free Clinic," (e.g., a health fair) so long as the Free Medical Clinic is "sponsoring" the health care practitioner pursuant the terms of the statute.¹⁴⁰

C. Volunteer Protection Act of 1997

For volunteers not covered by the FTCA, the Volunteer Protection Act of 1997 (VPA) may provide some coverage for services provided at Free Medical Clinics operated by nonprofit organizations. The VPA preempts inconsistent state laws unless the state in which the Free Medical Clinic operates has enacted a statute that explicitly makes the VPA inapplicable to civil actions where all parties are citizens of that state or the state has a law that provides more protections to volunteers than the VPA. Thus, a Free Medical Clinic should consider the preemption issue before relying on the VPA.

The VPA protects individual volunteers, including directors, officers, trustees, and direct service volunteers, but it does not protect the nonprofit organization that employs them. Under the VPA, "no volunteer of a nonprofit organization or governmental entity shall be liable for harm caused by an act or omission of the volunteer on behalf of the organization" if the volunteer (1) "was acting within the scope" of his or her responsibilities at the time of the act or omission; (2) "was properly licensed, certified, or authorized by the appropriate authorities for the activities or practice" in the state in which the alleged harm occurred; and (3) does not receive compensation or any other thing of value in lieu thereof in excess of \$500 a year.¹⁴¹

To the extent liability attaches to the volunteer's acts, each defendant is liable only "for the amount of noneconomic loss allocated to that defendant in direct proportion to the percentage of responsibility of that defendant," as determined by the trier of fact. Thus, a volunteer's monetary exposure greatly relies on the role he or she played in the plaintiff's care or at the volunteer organization as a whole. The VPA does not protect a volunteer's acts that exhibit "willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the individual harmed," or acts caused when a volunteer was operating a car, aircraft or other vehicle requiring a state operator's license and insurance.¹⁴²

With respect to damages, the VPA raises the malpractice standard from simple negligence to gross negligence and restricts the amount of punitive damages that can be awarded. The law provides that "no volunteer of a nonprofit organization . . . shall be liable for harm caused by an act or omission of the volunteer on behalf of the organization." Immunity is not absolute, however. If the harm is caused by "willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the individual harmed by the volunteer," the VPA will not prevent the plaintiff from pursuing a claim, including punitive damages, which the VPA otherwise prohibits. The VPA's limitations on liability do not apply to misconduct that constitutes a crime of violence, international terrorism, hate crime, sexual offense, civil rights violation, or misconduct occurring as a result of the volunteer's intoxication from alcohol or drugs. The VPA does not prevent the plaintiff from suing the organization that sponsors or supervises the volunteer; in this case, the Free Medical Clinic.¹⁴³



D. Charitable Immunity Laws

In addition to the limitations on reimbursement described above within the FTCA and VPA, there may be other restrictions on accepting payment for health care services rendered at Free Medical Clinics, such as state charitable immunity laws. Charitable immunity laws focus on liability protections for the *organization* rather than the individual volunteers or employees working on the organization's behalf. Forty-three states and the District of Columbia have enacted charitable immunity laws, which indemnify volunteers as if they were state employees or raise the negligence standard from simple negligence to gross negligence. Alaska, California, Massachusetts, Nebraska, New Mexico, New York, and Vermont do not have charitable immunity laws for volunteer medical providers, but they may receive protection under federal laws.¹⁴⁴

Under state charitable immunity laws, a volunteer medical provider may be found negligent but not liable if a patient's injury was caused by some other factor. Most states have changed the standard of care for malpractice liability for volunteer medical providers from simple negligence to gross negligence, indemnified them as government employees, or both. Nearly all charitable immunity legislation limits its coverage by restricting "the setting in which the healthcare can be delivered, [restricting] the type of care provided, or [requiring] patient notification of liability limitations." Some states also restrict the amount that can be recovered by a patient.

145

1. Liability Limitations

Charitable immunity laws that provide absolute and complete protection to nonprofit or charitable organizations are no longer in effect. Still, the common law doctrine of charitable immunity lives on in a limited capacity in nine states, defined either exclusively in case law or with statutory carve-outs. Free Medical Clinics operating in these states must refer to the most current case law within their jurisdiction to determine the scope of the charitable immunity protection. For example, the scope of the immunity may depend on how the charitable organization receives its funds, whether an employee or volunteer commits the negligent act, whether the state's charitable immunity law requires that the organization provide its services free of charge, or if the protection is voided by the presence of a liability policy. In certain states, the charitable immunity statute offers protection to the organization's officers and directors.¹⁴⁶

Charitable immunity laws today typically operate by setting a statutory cap on the amount a plaintiff may recover from the organization as damages in a civil suit. For instance, in Maryland, judgments are limited to the amount covered under the applicable liability insurance policy. Massachusetts, South Carolina, and Texas impose damage recovery caps for tort suits against charitable organizations in varying amounts. Generally, the immunity disappears if the organization failed to exercise ordinary care in the selection or retention of its volunteers or employees, or if the acts of such volunteers or employees amount to willful or wanton misconduct.

2. Conditioning Free Services on Ability to Pay

If a state provides any level of protection to a charitable organization that operates a Free Medical Clinic, the scope of the protection may depend on whether patients pay any amount for receiving health care services. In Ohio, a Free Medical Clinic that qualifies as a "nonprofit health care referral organization is not liable in damages to any person or government entity in a tort or other civil action" as long as the health care services were rendered by a volunteer health care professional or worker to an "indigent and uninsured person" as defined in the statute, and the health care professional or worker did not receive compensation. Thus, the Ohio statute does not afford charitable immunity to Free Medical Clinics that provide health care services to individuals who are not "indigent and uninsured" under the statute. By comparison, Arkansas common law provides that an organization's decision to provide services free of charge to those unable to pay is just one of many factors that a court considers in determining the applicability of complete charitable immunity.

In light of the requirements and limitations that some states place on immunity recipients, Free Medical Clinics should consider what operational practices may impact their ability to secure charitable immunity as certain operational practices may evidence the Clinic's charitable missions and support its efforts to obtain and maintain 501(c)(3) tax exemption. Charitable immunity requirements will vary by state, but certain operational practices may support a charitable immunity defense, such as clearly stating in patient intake forms, educational materials, and consent forms the Clinic's primary mission and status as a Free Medical Clinic; placing clear and visible signage throughout the Clinic that informs patients and visitors that the Clinic is a Free Medical Clinic; and explaining through informational materials what the Free Medical Clinic designation means in terms of liability. These types of operational practices are especially important where the state's charitable immunity laws prohibit Free Medical Clinics from accepting any fee, in whole or in part, or any in-kind contribution as payment for health care services rendered.

If a state allows the Free Medical Clinic to accept donations that are separate and distinct from the provision of services, Clinic organizers should develop a policy regarding the acceptance of fees (or partial fees) and donations. Clinics that have a donation program have found that many patients donate, which helps foster a commitment to and investment in the Clinic. The Free Medical Clinic will further benefit in obtaining and maintaining its charitable immunity if it has a written policy regarding the screening and evaluation process for its employees, interns, and volunteers. Such policies will demonstrate the diligence and care taken to engage only qualified and experienced medical professionals. The scope of the screening and evaluation should be determined based on individual Clinic resources, but the rationale and the process should be clearly documented.

Free and Charitable Medical Clinics receive little to no state or federal funding. They do not receive HRSA 330 funds and they are not Federally Qualified Health Centers or Rural Health Centers. Due to the limitations of charitable immunity and the fact that other types of immunity laws, such as Good Samaritan laws, typically protect only volunteers and not the Clinic itself, the Free Medical Clinic should consider obtaining other forms of insurance for its paid employees and the corporation itself. Some medical professionals may be able to rely on liability coverage maintained on an individual basis, but Clinic organizers should still review existing personal liability coverage on a case-by-case basis.

3. Other Laws

Sovereign immunity principles exist at the state level but are not addressed here as those principles are beyond the scope of this guidebook. Depending on how broadly the state applies the protection of sovereign immunity (e.g., to a Free Medical Clinic if the Clinic receives state agency funding or is operated through a state agency), the Clinic and its staff may enjoy additional protection from tort lawsuits and limits on its monetary liability. As with the other laws discussed in this guidebook, Clinic organizers must determine the applicability of their state's tort claims act.

CHAPTER 5: Insurance Coverage

A. Property and Casualty

Property and casualty insurance covers an organization against loss of physical property and income-producing potential due to incidents like fire, theft, vandalism, and other threats to the property. Clinic organizers should understand what type of property insurance the Clinic requires and what level of insurance will provide sufficient coverage. Four key terms to understand when evaluating a property insurance policy are:

- Actual Cash Valuation—The replacement cost minus depreciation. This coverage will only pay for the replacement of the Free Medical Clinic property minus the depreciation of the property.
- Replacement Cost Valuation—The replacement cost without deducting depreciation. This coverage will pay the cost of replacing the property regardless of the depreciation or appreciation.
- Agreed Amount or Functional Replacement Cost—The cost of acquiring another item or property that will perform the same function with equal efficiency, even if it is not identical to the item or property being replaced. This coverage is commonly used to value unique items.



♦ Extended Replacement Cost—The cost over the coverage limit if cost to reconstruct the property has increased.¹⁵¹

The limitations and exclusions of a property insurance policy may vary, but the most common limitations and exclusions include loss or damage caused by war, nuclear incidents, acts of terrorism, or floods and earthquakes. Casualty insurance covers organizations against loss caused when the organization is found legally liable for a third party's personal injury or damage to third party property. One of the most common forms of casualty liability that may impact a Free Medical Clinic is a slip and fall incident on the Clinic's premises.

B. Slip and Fall

Slip and fall injuries can happen at any time, anywhere, so Clinic organizers should consider "slip and fall" insurance to protect the Free Medical Clinic in the event of accidental personal injury on the Clinic's premises. The Clinic or its staff may be found liable for damages through a determination of negligence. Liability can arise if, for example:

- ♦ Staff created a slippery, torn, or otherwise dangerous surface to the floor;
- ♦ An employee knew about a slippery, torn, or otherwise dangerous surface to the floor and failed to repair or remove it; or
- ♦ The employee should have known about a slippery, torn, or otherwise dangerous surface to the floor because a reasonable person in that circumstance would have discovered the dangerous surface and repaired or removed it.¹⁵²

Slip and fall insurance generally includes two types of coverage: (1) liability coverage, which covers the cost of damages for the injured party when the Free Medical Clinic has been found negligent, and (2) medical payment coverage, which covers a certain amount of the injured person's medical expenses that stem from the slip and fall injury, even if the Free Medical Clinic is not found negligent.

C. Directors & Officers

As a nonprofit organization, a Free Medical Clinic will more than likely have a board of directors that will include both directors and officers. The Internal Revenue Service does not explicitly require nonprofits to have a board of directors, but strongly encourages it. State law also may impose governance requirements.¹⁵⁵

Director and Office (D & O) insurance can help assure directors, officers, and managerial staff that they will be covered, including legal costs, if they are found personally liable for the actions they undertake on the Clinic's behalf in their capacity as directors, officers, and managers. Directors and officers are subject to three basic duties in their capacity as directors and officers and may be found personally liable if any of the duties are breached:

- Duty of Care—The duty to act with care that a reasonably prudent person would use under similar circumstances, to act in good faith and in a manner that is in the Free Medical Clinic's best interests.
- Duty of Loyalty—The duty to refrain from using the director's position of trust and confidence to further the director's own interests, and to refrain from engaging in actions that would injure the Free Medical Clinic.
- ♦ Duty of Obedience—The duty to carry out the actions of a director in accordance with all applicable statutes and the charter of the Free Medical Clinic.¹⁵⁷

D. General Liability (Tortious Claims, Personal Injury)

Tortious coverage can protect a Free Medical Clinic if the Clinic is found liable for the intentional act(s) of one of its employees. Where property/casualty insurance only covers incidents that arise out of accidents, tortious insurance coverage goes beyond that and covers the Clinic for intentional acts that occurred with an employee's foresight, expectation or design. Unlike property/casualty coverage, tortious insurance also covers acts that result not only in personal injury but emotional, economic, or reputational injury. While intentional acts of one of its employees may not be at the forefront of the minds of Clinic organizers when evaluating the Clinic's insurance needs, tortious insurance coverage will nevertheless be an important type of insurance to consider.

E. Worker's Compensation

Worker's Compensation Insurance (Worker's Comp) can cover the Clinic's medical and legal expenses when an employee is injured or made ill by his or her work. Among other things, Worker's Comp generally pays for legal fees, employee medical expenses, and wages for employees who cannot work during their recovery.

F. Equipment Breakdown and Computer Coverage

Equipment breakdown insurance protects against breakdowns caused by power surges and operator error. It generally covers mechanical and electrical equipment, computers and communication equipment, and air conditioning and refrigeration systems. Equipment breakdown insurance can pay for the cost to repair or replace the damaged equipment, costs associated



with the time and labor to repair or replace the equipment, and the cost to replace spoiled stock or materials.

G. Commercial Crime Insurance

Commercial crime insurance provides protection against employee dishonesty, theft, burglary or robbery, and computer fraud.

H. Umbrella Insurance

Umbrella liability insurance provides additional protection if or when the existing liability insurance policies for the Free Medical Clinic cannot cover all of the expenses.

CHAPTER 6: Clinic Space

A. Leasing and Space Considerations

A Free Medical Clinic should lease office space near or within the demographic it is attempting to serve. Clinic organizers may want to conduct a population search through the Census Bureau to determine population characteristics and trends. A Clinic may also benefit from being close to other health care providers and referral sources, such as public housing, Goodwill-based organizations, the Salvation Army or other social program based institutions. Clinic organizers should consider other factors as well: (1) whether the location is zoned for dual purposes, specifically business and residential; (2) if the building contains environmental hazards that could interrupt Clinic operations and negatively impact nearby residents or tenants on other floors; and (3) whether the location has adequate visibility and enough parking to accommodate the population.¹⁵⁹

When choosing a location, the Free Medical Clinic should be aware of its unique and specific space requirements, the adequacy of existing utility systems, and even the positioning of weight bearing supports. Rental space design and calculated square footage is critical for the

Clinic to function optimally, including having enough examination rooms, sufficiently wide hall-ways, adequate work stations for staff, and a properly designed waiting room. A Free Medical Clinic must also make itself and its services accessible to individuals with disabilities and comply with the Americans with Disabilities Act (ADA), as is discussed in greater detail below.¹⁶⁰

B. Rent

As an initial step, Clinic organizers should secure a broker or tenant representative who understands and can identify the unique type of space needed to optimally operate a Free Medical Clinic. Aside from negotiating the base monthly rent rate, Clinic organizers should also understand how pass-through operating expenses (e.g., taxes, common area maintenance) and "expense stop" will be managed, and how much the landlord is willing to pay toward such expense, with any excess amounts billed to the tenant.¹⁶¹

Unlike hospitality and entertainment venues or other commercial leasing situations that allow rent to be dictated by the number of invitees or a percentage of revenue, federal health care regulations generally forbid rent to be determined by the volume and value of referrals or patients seeking health care. The Anti-Kickback Statute (AKS)¹⁶² was created in 1972 to prevent financial incentives (kickbacks, bribes, discounts, and rebates) from influencing where a beneficiary of a federal health care program receives medical treatment. The AKS requirements apply only if the Free Medical Clinic participates in Medicare, Medicaid or other federal health care program. If the Clinic provides free medical care without seeking reimbursement from a federally funded program, the AKS does not apply. Clinic organizers should, however, still check their states' laws to determine if the state has its own version of the AKS (e.g., Texas Anti-Solicitation Statute).

The AKS applies to leasing arrangements. If, for example, a Free Medical Clinic serving Medicaid patients rents office space from a physician who refers patients to the Clinic, the leasing arrangement will likely be scrutinized under AKS. Penalties for non-compliance include fines up to \$25,000, imprisonment, and possible exclusion from participation in government health care programs. A commonly used safe harbor for leasing arrangements is the space rental safe harbor, which states that remuneration (discounts, kickbacks, bribes or rebates) does not include any payment made by a lessee to a lessor for the use of premises so long as the following five conditions are met: (1) the lease agreement is set out in writing and signed by the parties; (2) the lease agreement specifies the premises covered by the lease; (3) if the lease provides access to the premises for periodic intervals of time, rather than on a full-time basis, the lease must precisely specify the schedule of such intervals, including their exact length and rent for such interval; (4) the term of the lease is for not less than one year; and (5) the aggregate rental charge is set in advance in arms-length transactions and is consistent with fair market value. Fair market value is the value of the rental property for general commercial purposes that is not adjusted to reflect the additional value

that one party (either the prospective lessee or lessor) would attribute to the premises as a result of its proximity or convenience to referral sources. Clinic organizers should engage an independent and qualified appraiser to make a written determination as to whether the rental rate meets the fair market value requirements as defined by the AKS.¹⁶⁴

C. Lease Compliance and Security

Lessors will likely negotiate that the Clinic use licensed professionals in good standing or have the Clinic's health care providers be supervised by those who have the requisite credentials. The lessor may also require that the Clinic deliver copies of all required valid permits, licenses, and certificates. Medical equipment and prescription drugs are highly susceptible to theft because of their high resale value, so the Clinic should either negotiate for adequate security (e.g., locks and alarm) or have the option to install a security system.

A Free Medical Clinic will likely possess medical or hazardous substances such as medical waste, ¹⁶⁵ nuclear waste, hazardous chemical substances, needles and similar medical sharp objects, volatile gases (e.g., oxygen, vacuum, medical air, nitrous oxide, nitrogen or carbon dioxide), ¹⁶⁶ and controlled substances ¹⁶⁷ in concentrations and quantities regulated by law. Given these substance and medical waste concerns, the lessor may require the Clinic to manage or remove such substances in a particular fashion or frequency. If possible, Clinic organizers should negotiate reciprocal representations and covenants identifying how each party create, release or be responsible for controlled substances and medical waste. Despite these efforts, the lessor will likely disclaim such obligations and contract that the Clinic properly store, retain, deliver, and dispose controlled substances and medical waste that meet local, state, and federal regulations and guidelines. If so, Clinic organizers should consider negotiating an adjustment to the operating expense before signing the lease.

D. The Americans with Disabilities Act

The Americans with Disabilities Act of 1990 (ADA) is a federal civil rights law that prohibits discrimination against individuals with disabilities in everyday activities, including the delivery



of medical services.¹⁶⁸ The ADA defines disability as "a physical or mental impairment that substantially limits one or more major life activities" of an individual; "a record of such an impairment;" or "being regarded as having such an impairment." A major life activity includes seeing, hearing, walking, bending, speaking, reading, and communicating. The ADA does not specifically define "substantially limits," but according to the federal regulations, the term applies if the impairment "substantially limits the ability of an individual to perform a major life activity as compared to most people in the general population." In 2008, Congress amended the ADA by adding provisions to emphasize that the statute should be applied broadly in order to achieve the ADA's overall purpose of eliminating disability discrimination.¹⁶⁹

Public accommodation is broadly defined in the ADA and includes the hospital and professional offices of health care providers. With limited resources, ADA compliance may be a challenge for many Free Medical Clinics. The Clinic may be able to rely on the affirmative defense that the accommodation would fundamentally alter the services provided or result in an undue burden. While this defense would not likely be accepted for hospitals and other health care entities, Free Medical Clinics may have a stronger case because they provide free or low-cost services to individuals who otherwise could not afford health insurance or are ineligible to receive benefits under a federal health program.

1. Physical Barriers

The ADA requires health care providers to provide auxiliary aids or services to reasonably accommodate and communicate effectively with both patients with disabilities and with companions who are individuals with disabilities.¹⁷² According to the Department of Justice's (DOJ's) Section on Disability Rights, "[a]ccessibility of doctors' offices, Clinics, and other health care providers is essential in providing medical care to people with disabilities." Under the ADA, health care providers must give persons with mobility disabilities full and equal access to their services and facilities and reasonable modifications to policies, practices and procedures if necessary, unless the modifications would fundamentally alter the nature of the services. The construction or alteration of a Free Medical Clinic is covered by Subpart D in the Code of Federal Regulations, "New Construction and Alterations." Clinic organizers and their counsel are encouraged to refer to the online publications provided by the DOJ for any issues regarding the construction or alteration of a Free Medical Clinic. As noted in the DOJ's publication, for example, it is generally not acceptable for a physician to examine a patient while he or she remains in a wheelchair; rather, the facility should provide the patient with an adjustable examination table.¹⁷⁴

2. Language/Communication Barriers

a. Hearing

The term "effective communication" varies based on the method of communication used by the patient; the nature, length, and complexity of the communication involved; and the context in which the communication is taking place. To ensure effective communication, the Free Medical Clinic should consult with the patient to determine the type of auxiliary aid needed, such as a sign language interpreter for the hearing impaired. The "Communication Request Form," included as Exhibits A and B in the Justice Department's settlement with INOVA Health Systems, is a good example of how the Clinic can determine a patient's auxiliary needs.

b. Speech

Free Medical Clinics must provide effective auxiliary services, such as a speech-to-speech transliterator, to those who have speech disabilities. This is recommended especially if the person will be speaking at length, which would likely include the patient's discussions with his or her physician at a Free Medical Clinic.

Consistent with the DOJ's Barrier-Free Health Care Initiative, the federal government targets medical services and facilities in their enforcement measures to make sure the ADA's goals are being met. Clinic organizers would therefore benefit from examining any issues related to ADA compliance to avoid civil penalties and compensatory damages.¹⁷⁷



PART III: OPERATIONAL ISSUES

CHAPTER 7: Recruiting and Training

A. Medical Professionals

A Free Medical Clinic should have at least one physician, in addition to other health care professionals, as part of the initial team. Often, this physician may initially serve as the Clinic's medical director. The team will work with Clinic management to identify the needs for additional volunteer medical professionals or employees based on the needs of the community's patient population. The team can also assist in recruiting volunteers through relationships with hospitals, multi-specialty physician groups, and other similar providers. These partnerships are critical to ensuring continuity of care for the Clinic's patients.¹⁷⁸ Recruitment of volunteer medical professionals is usually more easily accomplished through peer recruitment, so Clinic management should encourage its volunteers to reach out to colleagues and peers who may be interested in volunteering in the Clinic setting.

Free Medical Clinics may also utilize medical, nursing, and physician assistant students, as well as medical residents, to supplement the Clinic's workforce. Many students/trainees seek out such opportunities as part of their educational experience, and schools look to partner with organizations like Free Medical Clinics to provide a diverse training experience for its students. Before pursuing such an arrangement, the Free Medical Clinic should ensure it can comply with the appropriate supervision rules regarding students and trainees practicing at the Clinic. Regardless of the recruitment method, Free Medical Clinics must ensure that all medical professionals (volunteer or employed) have current and active licenses to practice.

B. Management Staff

The management staff typically includes a medical director, executive director, and Clinic/office manager. Given the role that philanthropy plays in funding Clinic operations, the Clinic may also have a development director on staff.

The Clinic's size and the skills and backgrounds of the management team may determine if these roles are combined. For example, one person may hold both positions of medical director and executive director or, in the case of volunteers, two people may share the role of medical director. Management-level positions are typically paid positions, but volunteers may perform certain tasks that are traditionally associated with those management roles.

The medical director oversees the Clinic aspects of patient care, ensuring that quality of care is not compromised, standards of care are met, and volunteers are properly equipped

to address patients' medical needs. The medical director is responsible for recruiting physicians, accepting referrals, overseeing chart reviews, monitoring and updating Clinic policies and procedures, serving on the Clinic's board of directors, and seeing patients periodically. The medical director can be a volunteer or paid position. A volunteer medical director should devote an amount of time that is reasonable for a volunteer; Clinic operators may, therefore, want to consider hiring an executive director or Clinic manager who also is a licensed medical professional, such as a registered nurse or midlevel practitioner, who can relieve the volunteer medical director of certain management activities, including quality assurance issues, patient record reviews, follow up on consults, and lab work.

The executive director acts as the chief executive officer for the Free Medical Clinic, ensuring that both the business and Clinic operations function appropriately. The executive director will often partner with the medical director to play a key role interacting with community organizations and seeking partnership opportunities so that the Clinic can fulfill its mission.¹⁷⁹

A Free Medical Clinic may be able to benefit from the expertise (e.g., information technology, finance, process improvement) of a partner hospital when specific administrative functions or assistance with special initiatives, such as installing a medical records system, is needed. Many hospitals encourage their Clinic and administrative leaders to use their skills in a community setting; such professionals may be ideal candidates for the Clinic's board of directors.

Once employees and volunteers are identified, the Clinic should adopt a screening and evaluation process to ensure the workforce is composed only of those who are qualified to serve in their assigned roles. The scope of such screening may vary based on Clinic resources.

C. Training

The Free Medical Clinic should have a robust training program for its employees and volunteers to ensure the entire workforce is trained on applicable laws and regulations, Clinic processes and procedures, and equipped to meet the needs of the patient population being served. Clinic organizers should develop a handbook of the Clinic's policies and procedures that can be easily accessed and provide employment and volunteer handbooks that explains policies regarding prohibition of harassment; non-solicitation; work hours; general conduct; safety; conflict resolution; expense reimbursement; emergency situations; and a drug-free work environment. The Clinic's workforce should be formally trained at least annually on these policies and procedures, including remedial training to address instances of non-compliance. Given the relatively small workforce, training may be conducted in person by a member of Clinic management who is responsible for workforce-related matters or a volunteer with expertise in employment matters.

Clinic organizers should fully document the process and procedures by which training content is developed, maintained, and administered to the Clinic's volunteer and employed staff. In many instances, it is valuable to maintain a list of who attended the training sessions and have each attendee sign an acknowledgement form regarding the training in which he or she participated.

The Clinic's workforce should also be trained on how to interact with uncooperative patients or those who cannot effectively facilitate their own care due to mental illness, physical disability, substance abuse, developmental delay, or other condition that makes self-care challenging. Equipping staff with the knowledge and resources to effectively communicate with their patients will help create a safe environment that encourages patients to seek care more consistently and become patients of the Clinic.

The Free Medical Clinic qualifies as a "provider/covered entity" under the Health Information Portability and Accountability Act (HIPAA) and is therefore required to comply with the Act. HIPAA requires that a Clinic's workforce be formally trained on the physical and technical safeguards that will ensure the protection of patients' Protected Health Information (PHI).¹⁸¹ This training should include specific state law requirements governing patient privacy, confidentiality, and the protection of sensitive information. Volunteer and employed health care professionals should also be trained on proper handling and disposal of blood borne pathogens, pursuant any standards set forth by the Occupational Safety and Health Administration (OSHA).¹⁸²

Orientation and training that educates and informs a Clinic's workforce about how to provide culturally competent care will help the Clinic meet the unique needs of the community's patient population, particularly immigrant communities. Such training should go beyond language requirements and include training about how certain health and psychological issues may impact certain immigrant communities. Moreover, individuals from immigrant communities may not know how to access health care in the United States or have differing views about the role a Free Medical Clinic should play in his or her family's health. In such situations, a Free Medical Clinic that is culturally competent may be able to provide options that include home remedies or other ways that the patient can receive care.¹⁸³

D. Affiliation with Health Occupation Schools

A Free Medical Clinic may benefit from developing a relationship with a local medical school and entering into a formal agreement to provide elective family practice rounds for medical students and residents. The Clinic's medical director should be involved in the process and help decide what level intern the Clinic can accommodate and how supervision will be provided. At a minimum, the medical director should review the intern's chart documentation and be available during the intern's hours to provide advice and consultation.

CHPATER 8: Operating the Clinic

A. Hours of Operation

Hours of operation will be driven largely by the unique needs of the Clinic's patient population, including the hours in which patients are typically available to seek health care services. For example, expanded hours will allow the Clinic to better serve patients who, due to occupational, familial, or other limitations are unable to seek care during usual business hours. The Clinic may also consider establishing other on-site locations, such as factories and agricultural centers or city missions, to further promote convenient access to health care. Grant funding may be available for these types of outreach Clinics. Some may also want to consider partnering with a transportation company or providing transportation through a Clinic-operated vehicle to help patients access care.

For many low-income, underserved, and uninsured patients, the Clinic often serves as their "medical home." It is unlikely, however, that a Clinic can remain open 24/7 due to financial and resource limitations. The Free Medical Clinic can benefit, therefore, from having a solid relationship with the local hospital and other local health care organizations so that together, they can educate the community about when it would be most appropriate to seek health care services from a Free Medical Clinic versus a hospital emergency department. Clinic organizers may also want to consider an around-the-clock answering service or "nurse-on-call" option to help facilitate patient questions and concerns after hours.

When scheduling staff and determining hours of operations, the Clinic will need to take into consideration the provisions of the Fair Labor Standards Act (FLSA), which establishes certain protections for workers, including minimum wage, overtime-pay, and other standards for employees in the private and public sectors. Hospitals and other institutions that are "primarily engaged in the care of the sick, the aged, or the mentally ill" are covered employers under FLSA Section 3(s)(1)(B), which may include certain Free Medical Clinics. Hest requirements may not apply to everyone, however, as many who work in Free Medical Clinics are either volunteers or fall under exemptions provided in the Act. Because volunteers donate their time and services, usually on a part-time basis, they are not considered employees and therefore are not covered by FLSA's overtime provisions. In addition, Clinic employees are often exempt from FLSA as professional employees (e.g., nurses, physicians). The U.S. Department of Labor (DOL) offers resources to help employers determine if they or members of their workforce are covered by FLSA, including tools to assess compliance.

B. Limited English Proficiency and Interpreters

Translators and interpreters play an important role in ensuring that a Free Medical Clinic provides culturally competent care. Title VI of the Civil Rights Act of 1964 (Title VI) prohibits discrimination on the basis of race, color, and national origin by organizations receiving federal assistance. Such discrimination may be found through an organization's failure to provide meaningful access to care through sufficient language assistance services to individuals who have Limited English Proficiency (LEP). 189

In 2003, the HHS Office of Civil Rights (OCR) revised and reissued its policy guidance on Executive Order 13166 and outlined four factors that institutions, programs, and providers should consider when determining the extent and type of language assistance that should be provided. The OCR's policy guidance gives small providers considerable flexibility in determining how to fulfill their obligations toward ensuring meaningful access to LEP individuals. Under the revised policy guidance, OCR will assess compliance on a case-by-case basis and will take into account the following factors: (1) the number or proportion of LEP persons eligible to be served or likely to be encountered by the recipient's program activity or service; (2) the frequency with which LEP individuals come in contact with the program,



activity or service; (3) the nature and importance of the program, activity, or service provided by the recipient; and (4) the resources available to the recipient, including costs. There is no one-size-fits-all solution for Title VI compliance with respect to LEP persons, and what constitutes "reasonable steps" for large providers may not be reasonable where small providers are concerned. Thus, smaller providers with limited budgets will not be expected to give the same level of language services as larger recipients. If a Free Medical Clinic needs help in determining the language program that will best meet the Clinic's particular needs, OCR offers technical assistance to recipients of federal funds. Regardless of whether Title VI applies to the Free Medical Clinic, OCR's policy guidance provides helpful considerations when developing an interpreter program.

C. Background Checks

The confidential nature of a patient's personal and medical information that is shared during patient encounters, and to which the Clinic's staff has access, requires that the Clinic conduct due diligence when hiring its employees and recruiting new volunteers. Effective screening measures such as conducting thorough background checks can help limit the potential for violence and patient abuse, protect the confidentiality and security of patients' Protected Health Information, and protect or minimize the potential for financial or reputational damage to the Clinic. Specifically, a Free Medical Clinic should (1) develop and implement policies promoting a safe work environment; (2) create and implement a pre-employment screening policy using reputable and certified background check products and services to ensure safer hiring practices; (3) follow all applicable rules and regulations, including, without limitation, the rules and regulations of the Fair Credit Reporting Act (FCRA); (4) establish criteria to evaluate the information and determine what will constitute disqualifying information from the outset; and (5) conduct periodic screening of employees to maintain a dependable, accountable health care workforce free of unlawful behavior.¹⁹⁰

CHAPTER 9: Patient Care Issues

A. Patient Intake

All patient care issues center around having a workforce that appreciates the socioeconomic challenges of its patients and provides an atmosphere of sensitivity to those needs. A relatively simple but effective patient intake practice is to ensure that intake forms are clear, concise and, if possible, in the language that is generally used by a majority of the Clinic's patient population (e.g., English and Spanish). The intake form should request only basic information that is essential for effective and safe care and reflect sensitivity to the patient's potentially controversial medical history, the patient's lack of formal health care experience, and the patient's limited access to advanced or even basic medical care. Clinic volunteers and employed staff should receive training on how to explain to the patient why the requested information is necessary and how to help the patient complete the intake form. To the extent resources are available, Free Medical Clinics should consider using translators or staff who are fluent in the patient's native language, which can positively impact patient outcomes because the patient's questions can be answered and health information and treatment recommendations can be more fully understood.

Due to implementation of the ACA, information related to residency status, which historically had not been requested, is now becoming more important. Legal residents may have access to insurance programs that were not traditionally available to them. Intake personnel should be able to effectively explain why this information is being requested. In an effort to diminish the negative effects of this new information request, Free Medical Clinics may offer a "prefer not to respond" option, which would cover undocumented patients from affirmatively stating they are not legal residents. Intake personnel should, however, encourage legal residents to answer affirmatively in an effort to enroll them in applicable health coverage programs. Many free and charitable Clinics have or work with financial counselors who can assist legal residents with applying for and enrolling in health care programs.

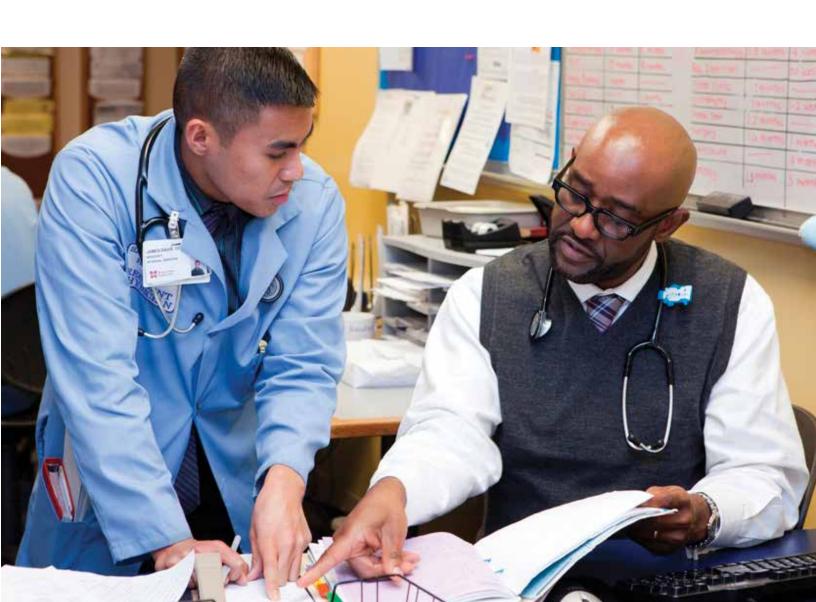
B. Patient History and Reliability of Patient Records

Accurate and complete information is critical to the safe and effective provision of health care services, but in the context of the Free Medical Clinic, the challenge lies in determining how much patient history is necessary and how reliable is this information. Unfortunately, there is no perfect answer.

An accurate medical history may be unavailable for a variety of reasons, including language barriers, the absence of previous health care services, physical disabilities, mental illness, and dishonesty. Clinics may find that certain patient populations are more inclined to provide incomplete information during the intake process, so it is important that Clinic staff understand the sociological barriers and work to address them. Establishing trust may become easier with repeated visits as the patient and the staff gets to know each other better. Emphasizing the Clinic's commitment to patient privacy and confidentiality throughout the intake and care process will help strengthen that trust.

Where medical records are available, Free Medical Clinics should use them to build and verify an accurate patient profile. Clinic providers should also make an effort to identify conflicts between medical evidence and patient claims or omissions to help guard the Clinic and the patients against negative consequences. A policy detailing the provider's role in this

process may be helpful. For example, reviewing the medical history with the patient to the extent there is concern about the history's accuracy will ensure that the provider reviewed the information with the patient to identify potential discrepancies that may negatively affect patient care. In addition, a Clinic's policy may require the provider to explain the objective consequences of noncompliance or dishonesty, which could include a discussion about the risks of drug interactions and other serious medical consequences that may result from incomplete or inaccurate information. Recruiting cooperative family members to help ensure and encourage compliance with provider recommendations may also be useful. Some situations may require more direct investigative steps to obtain accurate information from a patient, such as requesting random blood tests or monitoring the patient's consumption of medication. These actions can protect against noncompliance, dishonesty or poor memory due to mental illness or age. These aggressive practices, while helpful in capturing accurate information about an individual, may, however, also discourage patients from seeking and receiving care at the Clinic. Further, this approach may be subject to restrictions under state law.



Another way to promote safe and effective patient care and reduce potential liability is to have the Clinic ask its patients during the intake process and at each visit to acknowledge in writing that they are providing full and accurate information. Alternatively, the Clinic may have each new patient sign a comprehensive acknowledgement and agreement form indicating that he or she will continue providing full and accurate information. State law may dictate whether a Clinic can require these types of acknowledgements as a condition for accepting a patient. If it is permitted under state law, Free Medical Clinics should consider making the execution of such acknowledgement and agreement forms a condition to receiving health care services or medications.

C. Terminating the Patient Relationship

A Free Medical Clinic may find itself in the difficult position of needing to terminate a relationship with a patient. Because the mission of Free Medical Clinics is to provide services to the underserved, terminating a provider-patient relationship and prohibiting an otherwise qualified individual from receiving health care services may seem like undermining that mission. Situations do exist, however, where terminating the relationship is appropriate because the patient consistently fails to show up for appointments; is abusive or aggressive towards staff, volunteers, or other patients; consistently acts contrary to medical advice or is non-compliant with medication usage; or no longer qualifies for care by virtue of insurance status. Patients should understand the reasons that could lead the Clinic to refuse treatment and provide them with that information during the intake process.¹⁹² The American Medical Association's (AMA) Code of Medical Ethics and its Council on Ethical and Judicial Affairs provides guidelines for physicians who need to terminate a patient relationship. According to the Code of Medical Ethics, Opinion 8.115, physicians can terminate the patient-physician relationship but must give sufficient notice to the patient, relatives, or responsible friends and guardians so that another physician can be found.¹⁹³

State law varies with respect to the patient termination process. Some states explicitly recognize a physician's right under particular circumstances to terminate a patient relationship. In Michigan, a physician has the right to terminate a patient relationship so long as the patient is given reasonable notice so that the patient may secure another physician.¹⁹⁴ Other states, such as Louisiana, do not have well-defined requirements, and thus rely on common law theories of abandonment to determine whether termination is appropriate.¹⁹⁵ The Clinic should, therefore, understand what its state's law requires before implementing a decision to terminate its relationship with a patient.

In light of the AMA guidelines, various state law requirements, and the potentially hostile nature of patient termination, a Free Medical Clinic and/or its health care providers may

want to consider and adopt the following practice (or the steps required by law in the Clinic's state) when terminating a patient-provider relationship:

- Provide written notice to the patient that briefly explains why the relationship is terminating (the reason should be valid, such as non-compliance, failure to keep appointments, abusive behavior, etc.) and provide the date on which the relationship will terminate. A copy of the notice should be maintained in the patient's medical record along with documentation of the events leading up to the termination decision;
- Agree to continue providing treatment and access to services for a reasonable period of time, such as 30 days, so that the patient has time to secure care from another provider (the Clinic may consider extending that period for emergency services);¹⁹⁶
- ♦ Provide resources and/or recommendations to help the patient locate another provider; and
- ♦ Offer to transfer records to the newly-designated provider upon signed patient authorization.

D. Prescription Drug Management

1. Acceptable Ways to Obtain Prescription Drugs

Perhaps one of the most important services that Free Medical Clinics can offer is providing prescription drugs to patients who cannot afford them. Despite limited resources, Free Medical Clinics obtain prescription drugs through a variety of channels, including the donation of drug samples from licensed practitioners; through state prescription drug return, reuse, and recycling laws; and from pharmaceutical companies.

The Food and Drug Administration (FDA) recognized the importance of prescription drug sample donations and stated that donation of drug samples is permissible under the Prescription Drug Marketing Act, so long as certain requirements are met, including, but not limited to, the following:

- The donation must be in its original, unopened packaging, with labeling intact;
- ♦ The donation must be received by a designated and authorized employee of a charitable institution;
- ♦ A licensed practitioner or pharmacist at the charitable institution must examine the product before it is dispensed or further donated;

- ♦ All unsuitable donations should be destroyed or returned to the manufacturer;
- ♦ Accurate records must be maintained of the donation, distribution, inventory, return and destruction of donated products;
- Proper inventory must be maintained for all donations; and
- Drug samples must be properly stored.¹⁹⁷

State prescription drug return, reuse, and recycling laws likewise have explicit requirements. Most state laws require that donated medications be in sealed, tamper-proof packaging and that the products have at least six months shelf life remaining.¹⁹⁸ Some states limit the types of prescriptions that can be donated, as well as who can donate products and who can accept donations. For example, some state programs only accept cancer drugs, while others accept most prescriptions except narcotics, which generally may not be donated. State programs vary widely in terms of their success. lowa, in particular, has a robust drug recycling program. Between 2007 and 2012, lowa's drug recycling program reported \$5,896,000 worth of donated drugs dispensed to 26,800 eligible residents.¹⁹⁹

2. Security of Drugs

Free Medical Clinics providing prescription drugs must meet state and federal requirements regarding prescription drug security, which may include:

- Maintaining an alarm system to signal intrusion into the pharmacy area;
- Maintaining control over the pharmacy area;
- Prohibiting non-essential personnel into certain areas;
- Creating physical barriers to separate the pharmacy area; securing prescriptions in areas that are within the view of the pharmacist during pharmacy hours;
- Securely locking areas where pharmaceutical products are stored during all times the pharmacy is closed; and
- Acceiving pharmaceutical products during pharmacy hours to ensure proper handling at all times. Any time the pharmacist is not present in the pharmacy area of a Free Medical Clinic, the pharmacy area should be secured and inaccessible to the public and non-licensed persons.

Many laws governing the donation of prescription drugs prohibit donation of certain drugs, such as narcotics and medications used to treat insomnia or anxiety as such drugs require expensive special security measures that can be cost-prohibitive for Free Medical Clinics and other charitable entities.

In addition to maintaining the general security of pharmaceutical products, Free Medical Clinics may have reporting obligations to state and/or federal agencies in the event of a security breach. For example, federal guidelines require that charitable entities receiving donated samples report losses or suspected theft of relevant products to the FDA.²⁰⁰

3. License to Distribute Drugs

Charitable organizations are often required to obtain a license before distributing pharmaceutical products. Requirements vary by state, and some states will waive the license fee for registered non-profit entities. The requirement for obtaining a pharmacy license is not necessarily based on the types of drugs the Free Medical Clinic plans to disburse, although a license is not always required if the Clinic plans on disbursing only donated drug samples. Some states, however, require a license wherever prescription drugs are dispensed, regardless of the amount of drugs dispensed, making no exception, not even for Free Medical Clinics.²⁰¹

4. Recordkeeping and Inventory Management

Free Medical Clinics providing prescription drugs must meet state and federal requirements for recordkeeping and inventory management. Typically these requirements mandate the Clinic to maintain documentation of the following:

- The name of the donated prescription product or medical device;
- Strength and dosage form;
- Number of units donated;
- Manufacturer's lot number;
- Expiration date; and
- ♦ Name, address and phone number of the donor for the drug or device. 202

The Gary Burnstein Community Health Clinic in Pontiac, MI cares for over 1000 patients, providing over one million dollars' worth of free medication.

Some states also require that the Free Medical Clinic obtain a signed donation form from the donor, while other states may require records regarding the further donation of products or the inspection, inventory, disbursement, redistribution, destruction, or return of the donated products.²⁰³

Free Medical Clinics dispensing pharmaceutical products must meet state specific and federal inventory management requirements. Federal guidelines require an annual inventory of prescription sample stocks, with any discrepancies potentially investigated by the FDA. Free Medical Clinics also must comply with special handling instructions to ensure certain drugs are stored properly (e.g., refrigeration required).²⁰⁴ Storage requirements may be cost-prohibitive for certain products.

5. Affordable Prescription Drug Assistance Programs

Some pharmaceutical companies sponsor patient assistance programs that provide medications for free or at a reduced price. Qualification standards often vary in terms of who can receive assistance, and these programs often have an application process that the patient or the health care provider must complete. Patients can also look into the Partnership for Prescription Assistance, an organization sponsored by biopharmaceutical research companies that provides a portal through which patients can access over 450 prescription assistance programs, including approximately 200 programs offered by pharmaceutical companies.²⁰⁵

Many states sponsor prescription assistance programs for eligible populations, usually for seniors, persons with disabilities, or the uninsured. Some programs provide discounts only for eligible enrollees, while others provide a direct subsidy using state funds.²⁰⁶ In recent years, however, many of these state sponsored programs have ceased operation due to decreased funding.

Alternatively, Free Medical Clinics can contract with commercial pharmacies to provide free medication to patients and bill the Clinic at a discounted price. Many large commercial pharmacies also offer medication programs. Walmart, for example, has a \$4 program for a 30 day supply of certain prescriptions (\$10 for a 90 day supply);²⁰⁷ Walgreens offers a Prescription Savings Club;²⁰⁸ and CVS offers a Health Savings Pass that offers a 90 day supply for \$11.99 on certain medications.²⁰⁹ Other programs, such as the WellCard Health program, provide a prescription card so patients can obtain pre-negotiated savings on prescriptions at participating pharmacies.²¹⁰

CHAPTER 10: Patient Privacy and Record Keeping

Privacy and confidentiality of health information is a priority for any health care organization. This section discusses the application of federal and state laws on privacy and confidentiality of health information in the context of the Free Medical Clinic. Before revising existing policies and procedures or planning for future operations and projects, Clinic organizers should consult with legal counsel to determine their compliance obligations. This section is not intended to be an exhaustive discussion of patient privacy and record keeping issues but rather, a general overview to aid Free Medical Clinics.

A. Establishing the Medical Record

Most Free Medical Clinics have a system to store patients' health information in electronic or paper records. These records contain sensitive personal information, including past medical history, family history, social history, laboratory results, and treatment plans/instructions for the patient.²¹¹ A Clinic may need to use and/or disclose information in a patient's medical records for many reasons, including, but not limited to, communicating with other health care providers about previous or future medical care, transferring patients to another health care facility, billing, quality assurance, and mandatory reporting to law enforcement.



B. Privacy and Confidentiality

1. The Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law administered by the U.S. Department of Health and Human Services (HHS) that establishes a standard for the protection of health information.²¹² The HHS Office for Civil Rights (OCR) enforces HIPAA. There are four rules within HIPAA that govern the privacy and security of individually identifiable health information (also called Protected Health Information or PHI).

HIPAA applies to "Covered Entities." A Free Medical Clinic is a Covered Entity if the it (1) furnishes, bills or receives payment for health care in the normal course of business and (2) sends electronically any health information in connection with a covered transaction (for example, claims or encounter information, health care payment, coordination of benefits, claim status, or referral certification for which HHS has established standards under the HIPAA Transactions Rule)?²¹³

2. The Free Medical Clinic as a Business Associate

A Business Associate is a third party that has access to PHI in order to perform a function on behalf of the Covered Entity. Before a Covered Entity may disclose or allow access to PHI, the parties must execute a Business Associate Agreement that includes specific terms as required by the HIPAA's "Privacy Rule." The purpose of the Business Associate Agreement is to outline each party's obligations with regard to PHI and receive satisfactory assurances from the Business Associate that PHI will not be accessed, used, or disclosed in violation of HIPAA.²¹⁴ In some instances, a Free Medical Clinic may find itself in a "Business Associate" relationship if—on behalf of a Covered Entity and not as a member of the Covered Entity's workforce—the Clinic creates, receives, maintains, or transmits PHI for a function or activity regulated by HIPAA. In other instances, a Free Medical Clinic would not be considered a Business Associate. For example, HIPAA specifically excludes from the definition of Business Associate "a health care provider, with respect to disclosures by a Covered Entity to the health care provider concerning the treatment of an individual."²¹⁵

3. The Privacy Rule

The HIPAA Privacy Rule regulates how an individual's PHI may be accessed, used or disclosed by a Covered Entity. The Rule also allows Covered Entities to disclose (or permit access to) PHI to a Business Associate. ²¹⁶ Each access, use, or disclosure must be permitted by the Privacy Rule or be in accordance with a valid authorization from the individual who is the subject of the PHI. The Privacy Rule provides specific examples and detailed requirements for use and disclosure, including, but not limited to, treatment, health care operations such as billing and quality assurance, law enforcement/notification, and public health reporting.

The Privacy Rule gives the individual certain rights, such as the right to (1) access one's own PHI, (2) request restrictions on the use and disclosure of PHI, (3) amend one's PHI, and (4) request an accounting of disclosures.²¹⁷ These individual rights may depend on how PHI is stored and whether the information is stored in a "Designated Record Set." Finally, the Privacy Rule contains a set of administrative and other requirements that Covered Entities must follow, including distribution of a "Notice of Privacy Practices," workforce training requirements, appointment of a Privacy Officer, and implementation of privacy policies and procedures.²¹⁸

4. The Security Rule

The HIPAA Security Rule is a separate set of requirements for Covered Entities and Business Associates who maintain or transmit electronic PHI (ePHI). The Security Rule requires Covered Entities and Business Associates to implement administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and availability of ePHI.²¹⁹ This rule's requirements affect an organization's information technology infrastructure and addresses issues such as password strength, firewalls, encryption, and how information can be stored on hard drives, laptops, and mobile devices.

5. The Breach Notification Rule

The Breach Notification Rule requires Covered Entities to notify individuals and the OCR when an individual's PHI has been breached. A breach occurs when PHI has been accessed, used, disclosed, or potentially disclosed in a manner not permitted by the Privacy Rule.²²⁰ For example, a Covered Entity may be required to notify the affected persons if their PHI was lost, stolen or misdirected.

6. The Enforcement Rule

The HIPAA Enforcement Rule authorizes the OCR to investigate and impose penalties for HIPAA violations, ranging from \$100 to \$50,000 per violation, and up to \$1,500,000 for identical violations in a calendar year.²²¹ The OCR may refer a Covered Entity and its employees or agents to the U.S. Department of Justice for criminal investigation. In addition, Covered Entities and Business Associates may be randomly or selectively audited by the OCR to ensure compliance with the Privacy, Security, and Breach Notification Rules.

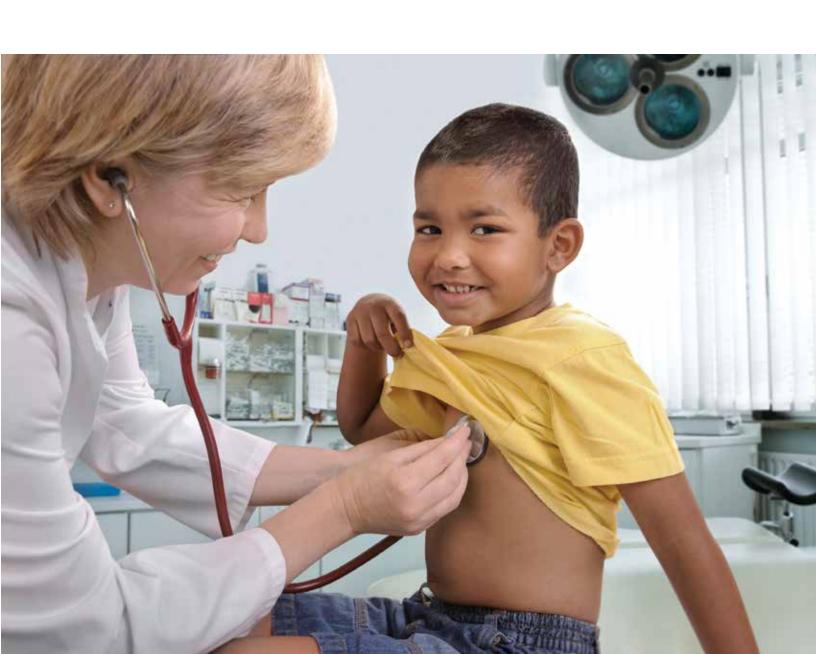
7. Alcohol and Drug Abuse Records

Free Medical Clinics that provide substance abuse treatment services are subject to additional privacy and confidentiality regulations beyond HIPAA. The federal regulations on Confidentiality of Alcohol and Substance Abuse Patient Records apply to federally-assisted alcohol and drug abuse programs and govern the confidentiality of and access

to substance abuse treatment information. This regulation includes procedures for disclosure in different situations, including mandatory disclosures, court orders, and disclosures pursuant to a patient's consent.²²²

8. State Privacy Laws

Most states have enacted laws and regulations related to the privacy and confidentiality of individuals' health information. Such regulations are usually set forth in facility and/or professional licensure laws, requiring both licensed health care facilities and licensed health care professionals to maintain the privacy and confidentiality of patients' health information. Some state regulations may be stricter than HIPAA and impose different or additional restrictions on a Free Medical Clinic's use and disclosure of patients' health information. When undertaking a HIPAA analysis, the Free Medical Clinic should include an evaluation and preemption analysis of state privacy and confidentiality laws and regulations.



C. Mandatory Reporting

While the Privacy Rule generally prohibits disclosures of health information, a notable exception exists for disclosures required by state laws, such as mandatory reporting of abuse victims or communicable diseases. These laws vary greatly from state to state, so the Free Medical Clinic should be knowledgeable about its state's mandatory reporting laws, particularly with regard to determining who is required to report and how the disclosure must be reported. Although most state laws protect persons complying with mandatory reporting requirements from civil liability, health care providers who voluntarily report are generally not afforded civil liability immunity. Several courts have, however, extended civil immunity to reports made in good faith but based on a negligent diagnosis. Disclosure should be limited to what is legally required as the HIPAA Privacy Rule only permits disclosure of the minimum amount of PHI necessary to achieve the purpose of the disclosure.

The majority of states have mandatory reporting requirements for child abuse, and the HIPAA Privacy Rule provision concerning child abuse permits Covered Entities to disclose PHI in accordance with state law. Free Medical Clinics should be aware of their state's specific requirements for reporting child abuse and know who is required to report. Some states have broadly required that all persons with certain knowledge of child abuse make a report, which could potentially impose obligations on a Free Medical Clinic's non-practitioner staff (e.g., the office clerk). Most states require reporting by those who, in their professional capacity, have reason to suspect child abuse, which would obligate health care providers observing evidence of abuse. Other states have enacted mandatory reporting laws specifying categories of people, usually including health care professionals, who are required to report evidence or knowledge of child abuse.

In addition, many states have compulsory communicable disease reporting laws requiring health care providers to inform public health authorities of specified communicable diseases, particularly for Acquired Immunodeficiency Syndrome (AIDS), Human immunodeficiency virus (HIV), and other Sexually Transmitted Diseases (STDs). If reporting of communicable diseases is required as part of a public health authority's collection of disease information, such reporting would be permitted under the Privacy Rule provision that allows disclosures of PHI (generally, the patient's name, age, sex, address, and details of the illness) for public health activities. Free Medical Clinics should refer to specific state laws to ensure disclosure is limited only to the information required.

D. Medical Record Practices

Patients' PHI is generally stored in an electronic medical record (EMR) or on paper (the patient's medical chart). All medical records, originals and accurate reproductions, must be available upon request.²²³ A patient's medical record may only be accessed by those at the Free Medical Clinic who have legitimate reasons for accessing the patient's medical chart or EMR.

E. Responding to Record Requests by Other Providers

HIPAA's Privacy Rule protects an individual's health information, but exceptions exist to avoid creating unnecessary barriers to health care delivery. For example, although health care providers are generally prohibited from releasing medical records or other health information without the patient's authorization, HIPAA's Privacy Rule allows for exceptions when the prohibition would interfere with access to quality health care. To avoid interfering with an individual's access to quality health care, the Privacy Rule permits Covered Entities to disclose health information and medical records for treatment, payment, and health care operation activities unless the disclosure is prohibited under 45 C.F.R. § 164.502(a)(5)(i) or requires an authorization under 45 C.F.R. § 164.508(a)(2) and provided that the disclosure "is consistent with other applicable requirements of" Subpart E. Other exceptions include situations that involve providing health care to a prison inmate, providing emergency treatment, or disclosing PHI because the individual is incapacitated and unable to provide consent.²²⁴

F. Receiving Continuity of Care Documents from Other Providers

Health care providers may share health information for treatment purposes without obtaining a patient's authorization. Under HIPAA, treatment includes the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another. As a result, health care providers may share health information, without the patient's authorization, with Free Medical Clinics so that care is not interrupted unless state law otherwise requires a patient's authorization.

G. Responding to Record Requests from Law Enforcement Agencies

From time to time, law enforcement officials may require access to a patient's medical information or other evidence that is in the Free Medical Clinic's possession. Health information may be disclosed to them, however, only in certain situations. Clinic staff should receive training on how to cooperate with and respond to law enforcement officials while protecting patient privacy rights under HIPAA and state privacy laws. Where state laws are more restrictive than HIPAA, the state's privacy laws will apply (e.g., the health information may only be disclosed pursuant to court order under state law).

As a preliminary matter, Free Medical Clinics should confirm the law enforcement official's identity before providing a patient's health information. Except when required by law, disclosures to law enforcement are subject to the Free Medical Clinic's minimum necessary determination. While the Clinic may rely on the law officer's representations of what is minimally necessary for law enforcement purposes, such reliance should be reasonable under the circumstances and is not required. 228

1. Court Orders, Warrants, Subpoenas, and Summons

Health information is released to law enforcement officials pursuant a valid court order or court-ordered warrant, a subpoena or summons issued by a judicial officer, or a grand jury subpoena.²²⁹ The health information provided should be limited to the information described in the court-ordered document.

2. Administrative Subpoenas and Investigations

Health information can be released in response to an administrative request, such as an administrative subpoena or investigative demand or other written request from a law enforcement official. These requests must include or be accompanied by a written statement indicating that de-identified information cannot be used, and the information requested is relevant and material, specific, and limited in scope.²³⁰

3. Locating Certain Persons and Reporting Certain Crimes

A limited amount of health information (Limited Information) may be disclosed to law enforcement for purposes of identifying or locating a suspect, fugitive, material witness or missing person. The information must be limited to the minimum amount necessary and may only include name, address, date and place of birth, social security number, blood type and RH factor, injury, date and time of treatment, date and time of death (if applicable), and a description of distinguishing physical characteristics. Other information related to the individual's DNA, dental records, body fluid or tissue typing, samples, or analysis cannot be disclosed under this provision, but may be disclosed in response to a court order, warrant, or written administrative request.

Consistent with applicable laws and ethical standards, Limited Information about a suspected perpetrator of a crime may be reported to law enforcement when the report is made by the victim who is a member of the Covered Entity's workforce or when the Limited Information is used to identify or apprehend an individual who may have escaped from lawful custody.²³¹ Further, Limited Information may be disclosed for purposes of identifying or apprehending

someone who admitted participation in a violent crime if the Free Medical Clinic believes the individual may have caused serious physical harm to a victim, unless that admission was made in the course of or based on the individual's request for therapy, counseling, or treatment related to his or her propensity to commit this type of violent act, in which case such information may not be disclosed.²³²

Free Medical Clinics may disclose health information to law enforcement for purposes of responding to an off-site medical emergency—as necessary to report criminal activity—but only the information regarding the commission and nature of the crime may be disclosed; the location of the crime or any victims; and the identity, description, and location of the alleged perpetrator. This limitation does not apply in emergency situations involving abuse, neglect, or domestic violence.





Free Medical Clinics may respond to requests for health information regarding victims of violent crimes, but only if the victim agrees. If the victim is unable to agree due to his or her incapacity or other exigent circumstances, the Clinic may disclose the information if the law enforcement official represents that the PHI (1) is not intended to be used against the victim; (2) is needed to determine whether another was involved in the alleged crime; (3) the investigation would be materially and adversely affected by waiting for the victim's consent, and (4) the provider treating the patient believes in his or her professional judgment that disclosure is in the victim's best interest.²³³

Free Medical Clinics may disclose health information to report abuse, neglect, and domestic violence to the agency or law official authorized by law to receive such reports. In the case of adult abuse and neglect, reporting is permitted if (1) the adult agrees; (2) the report is required by law; or (3) if expressly authorized by law and, based on professional judgment, the report is necessary to prevent serious harm to the individual or others, or in certain other emergency situations. If an adult's permission is not obtained, he or she must be notified of the report, unless the treating health care provider believes in his or her professional judgment that informing the patient would place the individual at risk of serious harm or the treating health care provider believes that informing the patient's personal representative would not be in the patient's best interest because the personal representative was responsible for the abuse, neglect or injury.²³⁴

4. Prevention of Physical Harm

When consistent with applicable law and ethical standards, a Free Medical Clinic may disclose health information to law enforcement officials if reasonably believed necessary to prevent or lessen a serious and imminent threat to the health or safety of an individual or the public.²³⁵ Such disclosure may also be required in connection with the ethical duties of licensed providers or in connection with state law, such as the duty to warn potential victims of violent crime.

5. Inmates in Custody

Free Medical Clinics may disclose health information to law enforcement officials about inmates and others in custody if the information is needed to (1) provide health care to the individual; (2) protect the health and safety of the individual, other inmates, officers or employees of the correctional institution, including those who are responsible for transporting and transferring inmates; and to (3) administer and maintain the safety, security, and good order, including law enforcement, on the premises of the correctional facility.²³⁶

6. Specialized Government Functions

Free Medical Clinics may disclose health information to federal officials authorized to conduct intelligence, counter-intelligence, related investigations, and other national security activities under the National Security Act, or to provide protective services to the President and others.²³⁷

7. Medical Examiners and Coroners

Free Medical Clinics may disclose information to medical examiners or coroners to assist them in identifying a decedent, determine the cause of death, and carrying out their authorized duties.²³⁸

8. Sensitive Health Information

Psychotherapy notes may only be disclosed to law enforcement when authorized by the patient or required by law.²³⁹ Substance abuse treatment records created by federally assisted alcohol and substance abuse programs may only be disclosed to law enforcement absent a patient's consent when ordered by a court.²⁴⁰ States may also limit permissible disclosure of substance abuse records to law enforcement to those who have been specifically compelled by court order or if the patient has specifically authorized disclosure in writing. Similar protections may exist under state law for various forms of other sensitive health information such as mental health records, HIV status, STD information, genetic information, and certain reproductive information.

The Brooklyn Free Clinic in Brooklyn, Ny is more than a primary care clinic for the uninsured. It is a community resource that provides weekly workshops, wellness groups, and other services to the city as a whole.

H. Worker's Compensation

HIPAA permits employers, workers' compensation insurance carriers, physicians, and other participants in the workers' compensation system to share PHI with each other in connection with a worker's compensation claims. Due to the significant variability of workers' compensation laws among the states, HIPAA permits disclosures of health information in a number of different ways. HIPAA specifically allows three exemptions if the disclosure is (1) "[a]s authorized and to the extent necessary to comply with laws relating to workers' compensation or similar programs established by law that provide benefits for work-related injuries or illness without regard to fault"; (2) required by state or other law, in which case the disclosure is limited to whatever the law requires; or (3) for the purpose of obtaining payment for any health care provided to an injured or ill employee.²⁴¹ It is not necessary to obtain an individual's HIPAA authorization if one of these exceptions applies.²⁴²

In addition, the individual seeking workman's compensation cannot require the Covered Entity to withhold his health information under 45 C.F.R. § 164.522(a). A Covered Entity may disclose PHI to worker's compensation insurers and others involved in the system where the individual has provided his or her authorization to release such information to the entity. Essentially, HIPAA permits a Covered Entity to disclose any PHI in conjunction with a worker's compensation claim as long as the Covered Entity limits the disclosure to the minimum amount necessary to address the worker's compensation claim.²⁴³

I. The Family Medical Leave Act

The Family and Medical Leave Act (FMLA) allows eligible employees of covered employers to take unpaid, job-protected leave for certain family and medical reasons. These medical reasons include the "serious health condition" of an employee's spouse, child, or parent, or the employee's own "serious health condition" that prevents him or her from performing the essential functions of the job. To assess whether an employee has a "serious health condition," an employer can require sufficient medical information to support an employee's request for family medical leave. If the employee fails to provide this information upon request, the employee will not qualify for FMLA.

HIPAA generally restricts a health care provider from disclosing a patient's PHI to third-parties, including employers, but if the employee authorizes his or her health care provider to complete the medical certification form and personally requests a copy for his or her employer, HIPAA will not impede disclosure of that employee's PHI. On the other hand, if the employer requests that the health care provider send the complete certification form directly to the employer, HIPAA will require the health care provider to obtain a valid authorization from the employee before the health care provider can share the PHI with the employer.²⁴⁴

A medical certification should state the following: (1) the date the condition commenced; (2) appropriate medical facts regarding the condition; (3) a statement that the employee is needed to care for a covered family member or a statement that the employee is unable to perform the essential functions of his or her job; (4) dates and duration of any planned treatment; (5) a statement of the medical necessity for intermittent leave or leave on a reduced schedule; and 6) the expected duration of such leave.²⁴⁵

J. The Americans with Disabilities Act

The Americans with Disabilities Act provides employees with disabilities limited workplace privacy protections. Employers with more than 15 employees may not ask job applicants about medical issues or require a physical examination prior to offering employment. After employment is offered, an employer can only ask for a medical examination if it is required of all employees holding similar jobs.²⁴⁶ Medical information acquired during the exam must be maintained in separate medical files and treated as confidential medical records.²⁴⁷

K. Record Retention, Storage, and Destruction

Many states have unique medical record retention laws that vary by setting or type of record. Federal law, payers, and regulatory or accrediting agencies also may have additional regulations governing record retention. The Free Medical Clinic should be familiar with all applicable regulations and abide by the most stringent. While HIPAA does not include medical record retention requirements, it does require that Covered Entities apply appropriate administrative, technical, and physical safeguards to protect the privacy of medical records and other PHI for as long as such information is maintained by the Covered Entity. HIPAA also requires retention of certain required documentation for six years from the date of its creation or the date when it last was in effect, whichever is later.²⁴⁸

HIPAA requires that medical records, both paper and EMR, be legible, readily available upon request, and stored properly to protect against loss, destruction or unauthorized use. Specific to protecting the information stored in EMRs, HIPAA's Security Rule requires that health care providers set up physical, administrative, and technical safeguards to protect electronic medical information. Some safety measures include access controls (e.g., passwords and PIN numbers) to limit access to the information; encryption of stored information; and an audit trail, which records whom accessed the information and what changes were made at what time.²⁴⁹

Health care providers must also have in place "reasonable" safeguards for the security of paper medical records. At least minimally, the Free Medical Clinic should designate someone to be in charge of record security and have locked doors; authorized entry access to records; and locked, fireproof record storage. Locks should be changed on a regular basis or with a change of personnel, including passwords, access codes, or advanced recognition. Confidential materials should not be kept on a publicly accessible system, and a publicly accessible system should not be operated on the institution's internal system. Lastly, archival and/or backup records should be stored off-site.

HIPAA's Security Rule requires that Covered Entities implement policies and procedures to address the final disposition or disposal of electronic PHI and/or the hardware and electronic media on which the information is stored. The Rule also requires procedures for the removal of electronic PHI from electronic media before the media are made available for re-use. PHIPAA's Privacy and Security Rules do not require a particular disposal method, so Covered Entities should review their own circumstances to determine how they can safeguard PHI in the disposal process. Having sound policies and procedures in place will help the Covered Entity accomplish that. In determining what reasonable steps to take, Covered Entities should assess potential risks to patient privacy and the form, type, and amount of PHI to be disposed. PHI to be disposed.

Some examples of proper disposal methods for paper records may include shredding, burning, pulping, pulverizing, or rendering the record unreadable. Some examples of proper disposal for electronic records may include the use of software or hardware products that overwrite media with non-sensitive data; purging by degaussing or exposing the media to a strong magnetic field, resulting in disruption of the recorded magnetic domains; destroying by disintegration, pulverization, melting, incinerating, or shredding; or other methods, such as keeping labeled prescription bottles and similar forms of PHI in a secure area in opaque bags and using a Business Associate disposal vendor to remove, shred or otherwise destroy the PHI.²⁵² Whatever the disposal method, the Covered Entity must ensure that appropriate workforce members, either working on the premises or off-site, receive proper training and comply with the disposal policies and procedures of the Covered Entity.²⁵³

During the 1980s, the Fan Free Clinic in Richmond, VA established the first community-based HIV/AIDS outreach program in the state.

CHAPTER 11: Quality of Care and Patient Safety

A. Medical and Nursing Oversight

1. Supervisory Hierarchy

The hierarchical structure of a Free Medical Clinic will depend on multiple factors, including, but not limited to, the degree to which the Clinic's medical director/Clinic director is involved; volunteers' and employees' skills; and the Clinic's budget. Regardless of the hierarchical structure, the Clinic's staff and volunteers are responsible for ensuring continuity of care and efficiency in running the Clinic's operations. An example framework for a hierarchical structure might include the board of directors, medical director, executive director, Clinic volunteers, Clinic/office manager, receptionist/office staff, and a medical assistant. Other positions may include a nursing director, a training director/manager, and an interpreter coordinator depending on the community's demographics.²⁵⁴

The Free Medical Clinic relies heavily on its administrative staff to ensure efficient operation of the Clinic's day-to-day operations, from the receptionist who schedules patient appointments to the office manager who monitors the Clinic's inventory of supplies and supervises both paid administrative and volunteer staff. With respect to the Clinic's Clinic aspects, it is not uncommon for the medical director to work with the executive director to ensure the Clinic is fulfilling its charitable mission. In addition, hiring or recruiting and supervising qual-ified Clinic staff (employees and volunteers) and ensuring that standards of care are often the responsibility of the medical director.²⁵⁵

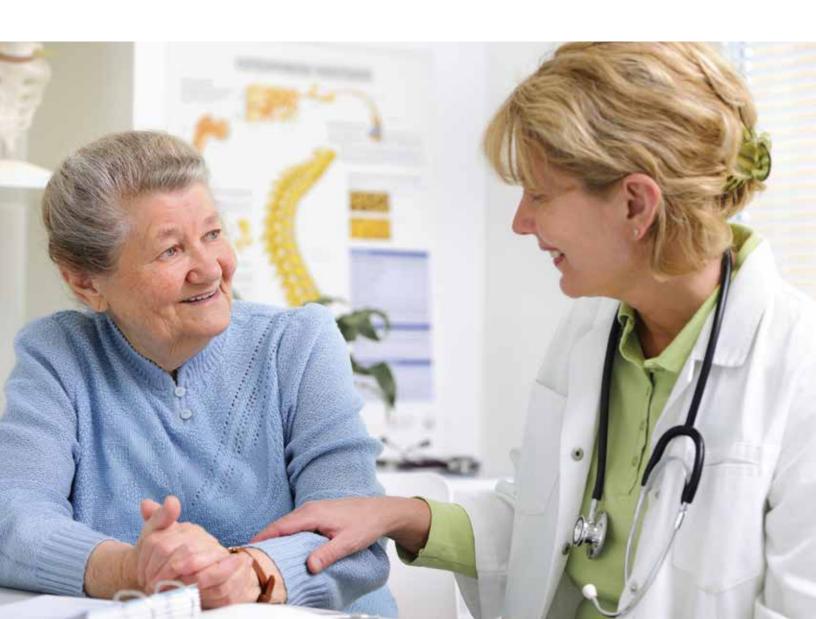
The Marshalltown Free Clinic in Marshalltown, Iowa has had much success with a particular volunteer structure that involves Clinic Coordinators. Under this approach, four volunteer nurses serve as Clinic Coordinators who act as head nurses. They are responsible for scheduling the nursing and non-medical staff for their assigned week. The Coordinators' duties may include (1) overseeing non-physician staff; (2) reporting inventory needs; and (3) arranging follow up care for patients.²⁵⁶

2. Staff Meetings and Continued Training

Good communication among Clinic staff plays a key role in ensuring patient safety and addressing quality of care issues that might arise. Regularly scheduled team huddles, weekly team meetings, production planning meetings, and "reflection" activities are all examples of how the Clinic's staff can optimize communication regarding Clinic operations and patient care.²⁵⁷ Implementing these types of meetings during which open dialogue, information-sharing, and collaboration is permitted can go a long way in fostering leadership and a patient-safety oriented culture.²⁵⁸

Generally, the purpose of the team huddle is to give the Clinic's health care providers an opportunity to review the day's schedule of patients and plan accordingly (e.g., likely noshows, a complex case, special equipment that might be needed to conduct an exam for a certain patient, what additional service can be provided to reduce the patient's likelihood of a re-visit). The team huddle may also be an opportune time to remind staff about certain policies and procedures, such as how to handle new and/or walk-in patients and discuss lessons learned.²⁵⁹

The weekly team meeting allows for a more concentrated period of time in which Clinic staff can discuss in greater detail their roles, responsibilities, opportunities for improvement, as well as other issues beyond the health care team (e.g., a problem with the location of a computer, practice-wide staffing issues). Production planning meetings focus on the Clinic's operational challenges (e.g., evaluating inventory of supplies against actual and expected demand), improvements, and successes.²⁶⁰



Integrating "reflection activities" into staff meetings may be help reiterate the Clinic's charitable mission and instill a sense of enthusiasm and ownership among Clinic staff. For example, the University of California San Diego's (UCSD) Student Run Free Clinic uses "learning circles" to build community and , share lessons learned on a variety of matters ranging from effective communication of empathy to operational efficiencies.²⁶¹

Continued health care and Clinic training through educational workshops, conferences, and classes contributes towards providing competent, quality health care.²⁶² The ECRI Institute's sample risk management plan indicated that "[f]acilitating and ensuring provider and staff participation in educational programs on patient safety and risk management" is one of the many functional responsibilities of a Free Medical Clinic's risk management program. In addition, Free Medical Clinics can also require that its staff receive annual educational training in the areas of safety, including, without limitation training on (1) cultivating a drug-free work environment; (2) safely collecting, handling, and disposing of blood borne pathogens; (3) administering basic life support skills; and (4) handling and managing a violent and/or difficult patient.²⁶³

Lastly, the U.S. Department of Health and Human Services Health Resources and Services Administration (HRSA) is dedicated to incorporating risk management activities in its approach to quality improvement and quality assurance. In its effort to support Free Medical Clinics, HRSA has provided risk management educational programs that can be accessed online through which the Clinic's staff can utilize supplemental training tools such as audio-conferences and webinars and receive Continuing Medical Education (CME) credits.²⁶⁴

3. Specialists Performing Primary Care Services

It is not uncommon for trained specialists and pediatricians to volunteer at Free Medical Clinics. Given a Clinic's focus on providing primary—as opposed to specialty—health care services to a mainly adult patient population, these specialists and pediatricians must perform primary care tasks that they otherwise do not perform on a day-to-day basis. Supervisions and proper Clinic training are therefore important so that the volunteer specialists and pediatricians can effectively address the primary care requests or concerns of the Clinic's patients. When, however, a Free Medical Clinic uses a specialist for his or her technical capacity and medical specialty, extra training or supervision is not required because the health care provider has been properly trained in that specialty and is not acting in a different capacity.

4. Coordinating Care with Social Workers and Behavioral Health Providers Often times, challenging psycho-social issues can complicate a patient's prognosis or path to healing and act as barriers to effective care coordination, such as noncompliance with treatment, lifestyle-related medical conditions, caregiving deficits, and lack of prior planning. The Free Medical Clinic should incorporate social and case management resources into its health care services as medical interventions alone constitute only one aspect the interdisciplinary approach to patient care.²⁶⁷

The Agency for Health Care Research and Quality defines "care coordination" as "... deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient's care to achieve safer and more effective care. This means that the patient's needs and preferences are known ahead of time and communicated at the right time to the right people, and that this information is used to provide safe, appropriate, and effective care to the patient." The National Coalition on Care Coordination defines "care coordination" as "a person-centered, assessment-based, interdisciplinary approach to integrating health care and social support services in a cost-effective manner in which an individual's needs and preferences are assessed, a comprehensive care plan is developed, and services are managed and monitored by an evidence-based process which typically involves a designated lead care coordinator." 269

In the Clinic's effort to better coordinate care, a social worker can tap into community resources that will help the patient maximize his or her functioning and independence after leaving the Clinic.²⁷⁰ While costly, utilizing an Electronic Health Record (EHR) system can further help coordination of care by integrating with other Clinic records systems (e.g., lab, oral, behavioral health); facilitating communications with patients; enhancing patient encounters, leading to increased productivity; and improving information sharing among and between practitioners.²⁷¹ If an EHR system is not a financially viable option, the Free Medical Clinic should consider other tools and resources that will help Clinic staff optimize information sharing and patient encounters.

Establishing partnerships with relevant community organizations that are representative of the entire continuum of care—other provider groups, community organizations, civic groups—will likely benefit the Clinic's internal coordination of care efforts and further help the Clinic build a system that encompasses the multidisciplinary aspects of health care. Marketing efforts and community outreach that identifies the Clinic as a new resource for the community will help increase the Clinic's visibility among and potential partnership opportunities with local organizations.²⁷²



5. Collaborative Practice Agreements for Physician Extenders

Appropriate supervision of Clinic staff is important to ensure patient safety and comply with the law. The "Risk Management" section of the FTCA application requests the applicant to "identify policies/procedures implemented regarding appropriate supervision of Clinic and non-Clinic staff[,]."In response to that inquiry, the Free Medical Clinic should describe its procedures regarding the supervision of mid-level providers.²⁷³ Pursuant to 21 C.F.R. § 1300.0, a mid-level practitioner is "an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, Clinic nurse specialists and physician assistants who are authorized to dispense controlled substances by the state in which they practice."

Collaborative Practice Agreements, Delegation of Services Agreements, and/or Supervision Agreements can serve as a means to show how mid-level providers are supervised. Such agreements are important from a Clinic standpoint as they memorialize the commitment to a collaborative practice, the purpose of which "is to deliver comprehensive care under which comprehensive care, in any setting, that best meets the needs of a particular practice population." ²⁷⁶

A Collaborative Practice Agreement is a "formal written statement addressing the parameters of the collaborative practice which are mutually agreed upon by [an] advanced practice registered nurse and one or more licensed physicians or dentists." State laws vary on whether Collaborative Practice Agreements and/or Delegation of Services Agreements are required, so Clinic organizers should research the matter for their particular jurisdiction. A typical Collaborative Practice Agreement identifies the names of the collaborating professionals and include/ indicate the advanced practice registered nurse (APRN)'s licensed APRN specialty (e.g., Family Nurse Practitioner (FNP), Adult Nurse Practitioner (ANP), etc.) and outlines the following:

- The APRN's responsibilities;
- ♦ Responsibilities of the collaborating physician(s);
- Methods of patient care;
- ♦ Expectations and requirements surrounding Clinic documentation;
- ♦ The process for diagnostic/lab requests; A process for medications/prescriptions that is in compliance with current state and federal laws;
- A process for radiology requests;
- ♦ A process, and expectations, regarding specialty consultations; and
- The obligations and duties of the collaborating physician;

Lastly, a provision about each participating practitioner's ability to terminate the collaborative practice agreement and signature blocks for each party (the APRN and participating physician) should be included at the end of the document. The APRN's signature block should allow for his or her signature, printed name, title, and if desired, his or her APRN license number, Drug Enforcement Agency (DEA) number, and APRN specialty. Similarly, the physician's signature

block may also include his or her state medical license and DEA numbers.²⁷⁸ Some states allow the collaborating physician to delegate health care tasks to a physician assistant, but these states require a written agreement between the physician and physician assistant. For example, Arizona requires that the agreement "state that the physician will exercise supervision over the physician assistant and retain professional and legal responsibility for the care rendered by the physician assistant." The agreement must be signed by both parties and updated annually. Arizona law also requires that the agreement be kept on file at the practice site and made available to the Arizona Regulatory Board of Physician Assistants on request, which randomly audits a minimum percentage of these agreements for compliance.²⁷⁹

In California, a Delegation of Services Agreement (DSA) is the means by which "[a] physician assistant may only provide those medical services which he or she is competent to perform and which are consistent with the physician assistant's education, training, and experience, and which are delegated in writing by a supervising physician who is responsible for the patients cared for by that physician assistant." Per California's Department of Consumer Affairs Physician Assistant Board, "[t]he DSA is the foundation of the relationship between a supervising physician and the physician assistant, and specifies the names of the supervising physicians and what types of medical services the physician assistant is allowed to perform, how they are performed, how the patient charts will be reviewed and countersigned, and what type of medications the physician assistant will transmit on behalf of the supervising physician."²⁸⁰

B. Quality of Care Review Issues

1. Medical Records

An accurate and complete electronic or written medial record serves many purposes, some of which include (1) providing a database for planning, evaluation, and treatment; (2) maintaining continuity of care; (3) documenting the patient's visit-to-visit condition; (4) documenting communications between the primary care provider and other health care professionals involved in caring for the patient; and (5) "provid[ing] written evidence that can be used to protect the legal interests of the [Free Medical Clinic]." 281

In efforts to mitigate the risk from documentation errors, the Free Medical Clinic should, among other things, ensure that each entry in the medical record is legible; each entry is signed clearly by the treating provider, including the appropriate identifier for the treating provider as required by state or organizational requirements; ambiguous words, symbols, or abbreviations are not used; and that the following are clearly documented and regularly updated:²⁸²

The Milan Puskar Health Right Clinic in Morgantown, WV has a staff of 21 and countless volunteers and provides more than 28,000 medical visits and dispenses free medication every year.



- Any discussions with the patient;
- Procedures performed and the amount, quantity, and names of materials used in procedures performed;
- The patient's treatment plan;
- ♦ The patient's health history;
- ♦ The patient's informed consent;
- ♦ The patient's informed refusal;
- The patient assessment;
- The treatment rendered:
- ♦ Objective findings; and
- ♦ Subjective complaints.²⁸³

Patient consent forms should not be too broad in scope and should explain the risks of certain procedures in lay terms and in a language or languages that are most commonly spoken and understood by the Clinic's demographics.²⁸⁴ For purposes of quality assurance, Free Medical Clinics may benefit from creating a small committee to periodically review charts for consistency or even ask a local hospital to exercise oversight over the Clinic's utilization reviews.²⁸⁵

2. State Medical Peer Review Laws

Many states have laws regarding quality reporting and medical peer review. Defined by the American Medical Association as "the process by which a professional review body considers whether a practitioner's Clinic privileges or membership in a professional society will be adversely affected by a physician's competence or professional conduct[,]"medical peer review is an important tool from a quality of care and risk management standpoint, as the outcome of a peer review proceeding can determine whether a physician's staff privilege or medical staff membership is granted, suspended, or revoked. The peer review process plays an important role in helping Free Medical Clinics and hospitals identify provider incompetence, thereby helping improve patient outcomes and quality of care.²⁸⁶

The laws of certain states recognize the importance of the peer review process and acknowledge that, "[b]y keeping information privileged, the peer review process serves to provide 'a safe forum in which medical professionals can review the quality of care and work to reduce medical errors." While the laws regarding whether peer review is privileged from litigation proceedings vary from state to state, certain states, such as California, lowa, Mississippi, Missouri, New Hampshire, and Pennsylvania, consider the peer review process privileged from litigation proceedings, including discovery, subpoena, or other means of "legal compulsion." In Pennsylvania, in addition to privileging the proceedings and records of peer review organizations from civil liability, the state's peer review statute provides immunity to those who participated in the peer review, so long as the participants used due care and did not act with malice.²⁸⁷ The state of Florida, however, has eliminated the protection it once afforded to the peer review process.²⁸⁸

C. Clinic Protocols

In 2011, the Institute of Medicine defined Clinic practice guidelines as "'statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options." Clinic protocols and practice guidelines, which are based on scientific data and expert opinion available at the time of a particular protocol's adoption can assist a multi-disciplinary team of health care providers make decisions about appropriate care for specific Clinic circumstances. When more data and information on a protocol's topic becomes available, the Free Medical Clinic should reevaluate the protocol and update accordingly.²⁸⁹

The Institute of Medicine of the National Academies recommends that the Clinic guideline development group be comprised of populations expected to be affected by the Clinic practice guidelines and protocols, and that "patient and public involvement should be facilitated by including [...] a current or former patient and a patient advocate or patient/consumer organization representative in the [Clinic guideline development group]."To help promote the effectiveness of patient and consumer representatives, the Free Medical Clinic should adopt certain strategies, which may include, but not be limited to, training the Clinic guideline development group members in appraisal of evidence.²⁹⁰

A Free Medical Clinic can use resources from professional organizations to create its own protocols, or the Clinic can adopt the Clinic protocols of another institution. For example, the Institute for Clinic Systems Improvement (ICSI) has a Prevention of Falls (Acute Care) Protocol that that the Free Medical Clinic can adopt or adapt, provided, however, that the Clinic comply with certain requirements, including, without limitation: ensuring that "ICSI receives appropriate attribution on all written or electronic documents [...]."²⁹¹

D. Continuity of Care

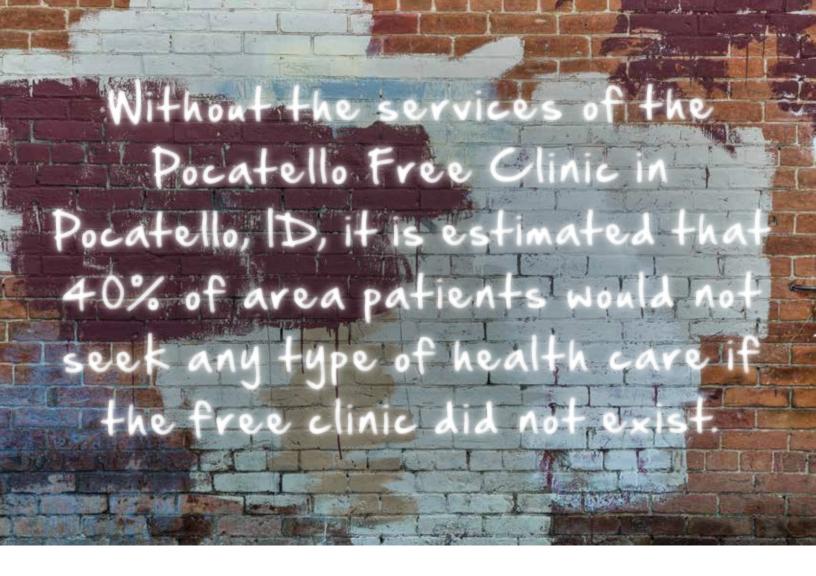
Continuity of care is concerned with the quality of care given over time, ensuring the patient receives the right level of care in the right location and that any provider caring for the patient has access to information about current and prior medical conditions and treatments or prescribed medications. Studies have shown that improved continuity of care has a direct positive effect on actual Clinic outcomes. Continuity of care also reduces the risks of unnecessary testing and the potential for medical errors. A Free Medical Clinic that does not effectively plan services and coordination of care risks losing local community support, which is crucial to the Clinic's success. Promoting continuity of care includes fostering continuous, caring relationships between patients and health care providers, as well as ensuring the safe, coordinated transition of patients between health care environments. A Free Medical Clinic's hours of operation and other factors that impact timely access to health care is critical to continuity of care. Continuity of care for the Free Medical Clinic can be assisted by collaborating with local hospital emergency departments, having processes in place to minimize walk-outs, and helping patients avoid missed appointments.

1. Collaborating with Local Hospital Emergency Departments

Free Medical Clinics generally provide primary, preventative, and chronic care in an ambulatory setting for underinsured patients with non-emergent conditions. Hospital emergency departments, on the other hand, provide acute care to stabilize any individual, regardless of the acuity of a patient's condition or ability to pay. As hospitals face decreasing reimbursements, collaborating with local Free Medical Clinics through referral programs can help hospitals control costs while strengthening the Clinic's mission and ability to provide a continuum of care.

Timely use of primary and preventive care services increases an individual's chances for better health, decreases his or her chances of being hospitalized for preventable conditions, and reduces the need for episodic care that patients would otherwise receive from hospital emergency departments because of medical conditions going undetected and untreated. The Free Medical Clinic can play an important role by educating the community on when it would be most appropriate to use the services of a hospital emergency department versus the Clinic setting. According to Teresa Brittain, Executive Director at the Free Medical Clinic of Oak Ridge, Free Medical Clinics should ensure that emergency department nurses and case managers are familiar with the Clinic's services.²⁹⁴

To strengthen the collaborative approach between hospital and Clinic, the Free Medical Clinic may partner with local hospitals to track hospital admissions and emergency department visits of Clinic patients and develop processes to schedule follow-up appointments. For example, a patient who received prenatal care from the Clinic can have her baby delivered by the same



treating physician at the partner hospital, and the pediatrician who rounds at the partner hospital's nursery can treat see the same child for primary care visits at the Free Medical Clinic.

2. Education and Marketing

Educating the community about the Free Medical Clinic's place in one's continuum of care is involves effectively marketing the availability and convenience of the Clinic's services and dispelling any notion that a visit to a hospital emergency room is required for every medical incident.. If communities are aware of nearby Free Medical Clinics and the services offered, people will be less likely to choose an emergency room for non-urgent care. There are several cost-effective means for marketing a Clinic's services. Free Medical Clinics can establish referral programs with local emergency departments by supplying them with prearranged lists of nearby Clinics and the respective services offered.²⁹⁵ Emergency department staff should be encouraged to refer uninsured, non-emergent patients who meet certain criteria to Free Medical Clinics. A case manager might also determine when

a Free Medical Clinic would be better suited than a hospital emergency department to manage a patient's care and make the referral after the patient is discharged.

In some instances, Free Medical Clinics and partner hospitals may consider a "deferral" program whereby the Free Medical Clinic provides care after a patient has been appropriately triaged in a hospital's emergency department. Studies have shown that Free Medical Clinics are capable of providing adequate care to deferred patients and that patients are generally open to being deferred from the emergency room.²⁹⁶ Partner hospitals must ensure their practices in referring or deferring patients are consistent with requirements under the Emergency Medical Treatment and Active Labor Act (EMTALA), which requires that a patient be appropriately triaged and stabilized before discharge or transfer to another medical provider.

Word-of-mouth can be another effective means to educate the patient community and create awareness about the Free Medical Clinic and its services. The Free Medical Clinic might verbally explain the primary care services it offers to its own patients or post the same information on the Clinic's social media networks. Ninety-two percent of consumers trust word-of-mouth recommendations from friends and family over all other forms of marketing and forty-two percent of consumers are more likely to purchase a product they learned about through social media.²⁹⁷ As such, Free Medical Clinics should use word-of-mouth and social media marketing to their advantage.

For a minimal cost, a Free Medical Clinic can post fliers throughout the community and create a website that contains information about the Clinic and the services offered. Free Medical Clinics can partner with local religious and social welfare organizations given the common clientele that each facility serves to help market services to the community. Teresa Brittain, the Executive Director of the Free Medical Clinic of Oak Ridge in Tennessee explained that "the ministers are the ones who will know who is sick and doesn't have insurance." The Clinic's management team should determine the best means to communicate with its specific patient population and, if needed, translate marketing materials into languages represented in the community.

3. Access to Emergency Room Records

Continuity of care is enhanced directly through the Free Medical Clinic practitioner's ability to access the medical records of patients treated by the local area hospitals. For example, some Clinics have systems on which they can track hospital admissions and emergency room visits, while others have privileges/agreements with nearby hospitals that allow them access to medical records of emergency room patients.²⁹⁹

Ideally, the Free Medical Clinic physician should be able to access such records electronically from within the medical offices of the Clinic. For example, due to privileging at Early Memorial Hospital in Blakely, Georgia, physicians at the local Free Medical Clinic can access in real time the hospital's electronic medical records on computers located at the Free Medical Clinic, thereby allowing the Clinic's physicians to access emergency room visit records, lab results, and other information on Clinic patients. Arrangements like the one between Early Memorial and its local Free Medical Clinics enable continuity of care and provide an important link between all the health care providers involved in caring for a patient. It is important to remain HIPAA-compliant as patient information is being shared among providers; however, there are exceptions that permit such sharing on a limited basis to ensure appropriate treatment of a common patient.³⁰⁰

Although many Free Medical Clinics have adopted electronic health records or other similar technology in recent years, many still find it cost-prohibitive. Under these circumstances, a Free Medical Clinic should consider collaborating with other organizations that provide services to patients to identify how they can share information to create comprehensive patient records while maintaining the appropriate privacy and security requirements for Protected Health Information under HIPAA.

Free Medical Clinics should also consider requesting that emergency department physicians either schedule for the patient a follow-up visit to the Clinic upon discharge or send the follow-up order to the Free Medical Clinic for scheduling. A patient is more likely to comply with medical follow-up orders when the follow-up appointment is made upon discharge from the emergency department.³⁰¹

4. Missed Appointments

Routinely and frequently missed appointments can negatively impact the patient's overall health and the provider's ability to monitor the patient's condition. Missed appointments can also take a toll on the Clinic's medical and administrative resources, resulting in increased wait times, unused capacity, and providers seeing fewer patients than they otherwise could. Reasons for no-shows are numerous, including challenges related to transportation, adverse weather conditions, co-morbidities, mental health conditions, general forgetfulness, and a lack of understanding regarding the importance of preventive care and ongoing treatment.

There are several strategies a Free Medical Clinic can employ to reduce its rate of missed appointments. One best practice is using telephone and text-message appointment reminders.³⁰⁴ A 2008 study found that patients were most likely to show up for their appointments when they received two different forms of reminders (e.g., a postcard in the mail and



a telephone call) before an appointment. The effectiveness of a particular reminder system depends, in part, on understanding both the overall patient population as well as the needs of the individual patient.³⁰⁵ For example, in a lower socio-economic area, many patients may not have cell phones or access to text-messaging services. Clinic staff should, therefore, ask patients how they prefer to receive appointment reminders during the patient intake process. Free Medical Clinics may also consider subscribing to an automated reminder service,³⁰⁶ which range in cost from \$50-\$600 per month depending on the size of the Clinic.

Free Medical Clinics may consider using a penalty system to serve as a deterrent for missed appointments. For example, St. Luke's Free Medical Clinic in South Carolina informs patients at the outset that he or she will be prohibited from using the Clinic's services after three missed appointments.³⁰⁷ To encourage compliance and follow-up, it will be important for Free Medical Clinics to provide clear and understandable information and guidelines for patients regarding the benefits of follow-up care and the potential consequences of missed appointments, such as termination of the Clinic-patient relationship.

Open access scheduling may also reduce missed appointments. This type of scheduling allows the Clinic to accept a certain amount of "walk in" appointments, which often results in a significant decrease in "no show" appointments. Walk-in availability gives patients the flexibility to receive treatment when a need arises and when other factors, such as child care, transportation, time off work, etc. makes it possible for the patient to visit the Clinic. Evening and weekend hours may also help reduce the number of missed appointments.

5. Reducing Wait Times

Many patients who seek care from Free Medical Clinics cannot afford to be absent from work for extended periods of time. Studies have shown that a large number of patients cite work obligations as the reason for walking out of a medical facility. The longer it takes a patient to see a doctor, the greater the chances are of the patient leaving without having been treated. Extended wait-times can prove administratively burdensome for Clinic and frustrating for patients.

Long patient wait-times may be due to inefficient communication systems between the front desk, nurses, and physicians and other inefficiencies in the Clinic's operations. If wait-times and walk-outs become an issue, the Clinic may need to consider investing in systems that improve overall operational efficiency. One best practice involves instituting a computerized patient flow management system that allows the front desk, nurses and physicians to communicate through a spreadsheet in real time. An example of a cost-effective patient flow

management system is Google Docs' "Patient Tracker," which is free and does not require additional expertise or system requirements. Google Docs' Patient Tracker uses a simple color- and letter-coding system on a shared spreadsheet that is updated in real-time. The color and letter coding indicates to Clinic staff when a patient has checked in, if the patient arrived late for his or her appointment and whether the physician has time to see that patient, when the patient has entered an exam room, and when the patient has concluded his or her appointment with the physician. Other more advanced patient flow management systems exist but may charge a monthly or annual fee. The patient has a simple and the patient flow management systems exist but may charge a monthly or annual fee.

E. Working with Other Providers and Collaborating for Affordable Care

A Free Medical Clinic patient may, from time to time, need specialty or advanced care that is beyond the scope what the Clinic can provide. Referring such patients to a specialist can present an issue if the patient is uninsured and/or low-income and the specialist does not accommodate prices accordingly.

One way to overcome this challenge may be for Free Medical Clinics to seek volunteer referral networks of specialists who volunteer their services uncompensated or at reduced rates. Under this model, network coordinators schedule patients' visits to specialists, arrange for transportation and translation where needed, and handle the paperwork. The volunteer specialist could then provide specialty care at his or her typical place of business. For example, a program in Central lowa called the "Volunteer Physician Network" allows free Clinics and local volunteer physicians to pool resources and deliver specialty services to uninsured, underinsured, or undocumented patients. Similarly, Clinics may consider partnering with local hospitals to provide services as hospitals generally have financial assistance policies in place to minimize or eliminate the cost of care for low-income, uninsured patients. Free Medical Clinics may also consider marketing directly to local specialists to expand its circle of referral providers. For example, volunteer physicians from the Clinic can conduct one-on-one recruitment of their physician colleagues from local hospitals.

F. Potential Issues and Protections Under the Anti-Kickback Statute

The federal Anti-Kickback Statute is a criminal statute that prohibits the exchange (or offer to exchange) of anything of value (called a "remuneration") in an effort to induce (or reward) the referral of federal health care program business. The Anti-Kickback Statute is broadly drafted and establishes penalties for individuals and entities on both sides of the prohibited transaction. Penalties for a conviction under the law may include a fine, imprisonment, and exclusion from any further participation in a federal health care program.

In recognition of the broad range of transactions potentially implicated by the Anti-Kickback Statute, certain types of payments are excluded from consideration by statute.³¹⁴ In addition, the U.S. Department of Health & Human Services (HHS) Office of Inspector General (OIG) has been given authority to adopt "safe harbors" to protect specifically identified business and financial practices from criminal and civil prosecution, provided they fall within the parameters defined to minimize the risk for potential corruption.³¹⁵ Transactions not specifically excluded or granted safe harbor protection are not per se violations of the Anti-Kickback Statute, but are evaluated by the OIG on a case-by-case basis based upon the totality of facts and circumstances.³¹⁶ Parties who are uncertain whether their arrangements qualify for exclusion or safe harbor protection may request an advisory opinion from the OIG.³¹⁷

There is no specific safe harbor that excludes business or financial arrangements involving Free Medical Clinics. Whether a certain business arrangement involving a Free Medical Clinic violates the Anti-Kickback Statute largely depends upon: (1) the structure of the Free Medical Clinic, and (2) the structure of the proposed business or financial arrangement.

First, concerning the structure of the Clinic in question, does it qualify as a Federally Qualified Health Centers (FQHC)?³¹⁸ Certain safe harbors protect specifically identified business practices involving FQHCs³¹⁹ (keep in mind that Free Medical Clinics and FQHCs are not the same. See Appendix H, Comparison of Free & Charitable Clinics to Federally Funded Clinics). Second, if the Free Medical Clinic does not qualify as an FQHC or fit squarely within the safe harbor, then it must evaluate its business arrangements on a case-by-case basis to determine whether those arrangements violate the Anti-Kickback Statute.

The HHS OIG has issued two opinions specifically involving Free Medical Clinics and the application of the Anti-Kickback Statute.³²⁰ In these cases, the OIG has asked the following questions in its analysis of the business arrangements proposed by the Free Medical Clinics:

- ♦ Does the business arrangement involve offering, paying, soliciting, or receiving any remuneration (anything of value) to induce or reward referrals of items or services reimbursable by a Federal health care program?
- Does the business arrangement involve giving something of value to a Medicare or Medicaid beneficiary that will likely influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program, including Medicaid?

If the arrangement appears to run afoul of the Anti-Kickback Statute, then each of the other regulatory safe harbors should be examined to determine any of them would protect the arrangement.³²¹

Although not a statutory or regulatory requirement, the OIG generally recognizes a Free Medical Clinic's good work and contribution to the public good in their advisory opinions. The central concern of the law is whether the business arrangement would likely result in fraud or abuse. Free Medical Clinics should consider the foregoing analysis before entering into any business or financial arrangements, seek legal counsel, and, when necessary, submit a request for an advisory opinion to the OIG.

G. Diagnostic Test Results

Many Free Medical Clinics provide laboratory services on site or by arrangement with an offsite facility. The Clinic Laboratory Improvement Amendments (CLIA) regulates all lab testing on humans. A CLIA Certificate of Waiver allows medical facilities, including Free Medical Clinics, to perform tests that have been determined by the FDA or CDC to be so simple that there is little risk of error in the results.³²² To date, approximately 120 types of tests are CLIA-waived, including blood tests, urinary exams, pregnancy tests, and HIV tests.³²³ Most lab testing done at Free Medical Clinics can be CLIA-waived and therefore do not require the services of specialists or need to fulfill most of CLIA's requirements. Physicians and nurses typically conduct tests at CLIA-waived sites, but there is no specified level of education or training required of testing personnel at CLIA-waived facilities.³²⁴

Due to regulatory hurdles and costs, Free Medical Clinics should carefully consider the costs and benefits of offering an on-site CLIA-certified lab for more complicated tests that would not be covered by a CLIA waiver. For complex laboratory testing services that fall outside the realm of CLIA-waived tests, the Clinic could refer to physicians in a volunteer network or partner with local hospitals that may be willing to take turns with other hospitals in providing laboratory testing as an in-kind contribution to the Clinic. Stephanie Garris, Executive Administrator of Grace Medical Home, a large free Clinic in Orlando, Florida, noted how thankful she was that the two large health systems—Orlando Health and Florida Hospital—donate laboratory services to her Clinic. In addition, doctors who operate local labs and radiology facilities can be another source of diagnostic help, reducing the Clinic's need to spend time and money providing lab testing on-site.

H. Coordinating with Other Social Welfare and Community Organizations

Local social welfare organizations can be powerful tools for community-based health initiatives and programs because of the vital social, public health, mental and behavioral, and general welfare services they provide to the community. Free Medical Clinics should consider collaborating with the organizations that are most compatible with the Clinic's mission so as to gain community exposure and support while simultaneously delivering care to the underprivileged. These organizations will likely welcome the additional help that Free Medical Clinics can provide, and the Clinic will likely benefit from the increased exposure. A Free Medical Clinic may collaborate for example, with the local United Way—an organization centered on youth education—to provide free health exams for children involved in the United Way program. Similarly, a Free Medical Clinic can coordinate with a local Metropolitan Ministries organization to provide health services to the poor and homeless. In the end, the goal of such partnerships should be to maximize available resources and create an effective and as comprehensive of a medical home for patients seeking care from a Free Medical Clinic.

I. Security Issues for Staff and Patients

1. OSHA Standards and Violence

The Occupational Safety & Health Administration (OSHA) sets out regulations that must be followed in most workplaces, including Free Medical Clinics. Additionally, several states have OSHA-approved state plans that govern the health and safety of workplaces. Clinic organizers and operators should review the OSHA standards or OSHA-approved state standards in their entirety to ensure their Clinic is operating legally. A comprehensive list of OSHA regulations is available at www.osha.gov.

According to OSHA, those who work in health care are at an increased risk of workplace violence. The U.S. Department of Labor suggests that an employer "establish a zero-tolerance policy toward workplace violence against or by their employees." The particular circumstances and geographies of Free Medical Clinics also make them more susceptible to potential criminal or violent behavior from patients or visitors. Best practices offered by OSHA to help ensure the safety of a Clinic's staff, patients, volunteers, and visitors involves (1) installing security systems (i.e., surveillance cameras and alarm systems); (2) establishing a buddy system for employees leaving workplace premises; and (3) providing safety education programs for employees, including training about how to handle a potentially violent

patient or how to recognize certain signs that may indicate agitation, intoxication, mental illness, or other condition that might impact the provider-patient interaction.³³³

2. Coordinating with Law Enforcement and the Use of Crime Detection Systems Collaborating with the local police department and state prosecutors can also assist in controlling violence. In addition to providing resources to assist with incident management, law enforcement can offer strategies and guidance on issues of violence impacting the local community and how the Free Medical Clinic can protect its employees, volunteers and patients. OSHA suggests that medical facilities provide police departments with a layout of the facility for more efficient investigations. Clinic staff should be trained on the procedures for requesting police assistance. Regular meetings attended by police precincts and the Clinic's health care providers can be another way in which open discussions can take place about best practices for patient, staff, and community safety.³³⁴

Some Free Medical Clinics have invested in metal detectors as a means of crime prevention and safety in areas with high crime rates. Within a matter of days, a Clinic in Massachusetts discovered over thirty concealed weapons on patients with its metal detector. If a Clinic decides to install metal detectors, it is important to develop a procedure for staff once weapons are detected. This plan should include processes for dealing with patients who refuse to surrender detected weapons, storing confiscated weapons, returning confiscated weapons, and alerting the proper authorities.³³⁵

With prices ranging from \$1,000 to \$30,000, standing metal detectors can prove expensive for a nonprofit Free Medical Clinic. Further, although the prices for handheld metal detectors are reasonable, Clinics may ultimately spend a considerable amount of resources to employ their operation (i.e., hiring a security officer to operate the handheld device). Finally, the presence of metal detectors in a Free Medical Clinic may give a negative perception to patients and the community-at-large. If a patient's first experience with a Free Medical Clinic is walking through a standing metal detector or being scanned by a security officer, they may feel uncomfortable, unsafe, and possibly unwelcomed. Crime rate information and related facts regarding the Clinic's location should be considered before implementing a metal detector, or crime detection or surveillance mechanism. As an alternative, some Free Medical Clinics may install panic buttons for security purposes, which would allow a certain level of security without impacting the warm and welcoming environment that a Clinic wants to provide for its patients.



Website Links to Governmental and Non-governmental Organizations Associated with Free Medical Clinics

Organization	URL	Contact Email	Phone Number	Address
		Alabama		
n/a	n/a	n/a	n/a	n/a
		Alaska		
Alaska Primary Care Association, Inc.	www.alaskapca. org	info@alaskapca.org	(907) 929-2722	903 W Northern Lights Boulevard., Suite 200 Anchorage, AK 99503
		Arizona		
Arizona Association of Community Health Centers	www.aachc.org	info@aachc.org	(602) 253-0090	700 East Jefferson Street, Suite 100 Phoenix, AZ 85034
		Arkansas		
Arkansas Association of Charitable Clinics	n/a	chuckm@aac Clinics.org	(501) 520-0823	133 Arbor Street Hot Springs, AR 71901-3535
Community Health Centers of Arkansas, Inc.	www.chc-ar.org	n/a	(501) 374-8225	420 W 4th Street, Suite A North Little Rock, AR 72114
		California		
California Association of Free & Charitable Clinics, Inc.	www.california freeClinics.org	n/a	(805) 433-5279	P.O. Box 357 Tulare, CA 93275
Community Clinic Association of Los Angeles County	www.ccalac.org	n/a	(213) 201-6500	700 S. Flower Street, Suite 3150 Los Angeles, CA 90017
California Primary Care Association	www.cpca.org	webmaster@ cpca.org	(916) 440-8170	1231 Street, Suite 400 Sacramento, CA 95814
		Colorado		
Colorado Community Health Network	www.cchn.org	info@cchn.org	(303) 861-5165	Colorado Community Health Network 600 Grant Street, Suite 800 Denver, CO 80203
ClinicNET	www.Clinicnet.org	info@Clinicnet.org	(720) 863-7800	3033 S. Parker Road, Suite 500 Aurora, CO 80014

Organization	URL	Contact Email	Phone Number	Address
		Connecticut		
Community Health Center Association of Connecticut	www.chcact.org	ask@chcact.org	(860) 667-7820	100 Great Meadow Road, Suite 400 Wethersfield, CT 06109
		Delaware		
Mid-Atlantic Association of Community Health Centers	www.machc.com	info@machc.com	(301) 577-0097	4319 Forbes Boulevard Lanham, MD 20706
		District of Columbia		
District of Columbia Primary Care Association	www.dcpca.org	n/a (contact form only)	(202) 638-0252	1411 K Street NW, Suite 300 Washington, DC 20005
DC Healthcare Alliance	http://dhcf.dc.gov/ service/health- care-alliance	n/a	(202) 639-4041	n/a
		Florida		
Florida Association of Community Health Centers	www.fachc.org	fachc@fachc.org	(850) 942-1822	2340 Hansen Lane Tallahassee, FL 32301
Florida Health Miami-Dade County	www.dadehealth. org/index.asp	Call.Center@dbpr. state.fl.us	(305) 324-2400	n/a
Florida Association of Free Clinics	www.fafcc.org	n/a	n/a	n/a
		Georgia		
Georgia Association for Primary Health Care	www.gaphc.org	javent@gaphc.org	(404) 659-2861	315 West Ponce de Leon Avenue, Suite 1000 Decatur, GA 30030
Georgia Charitable Care Network, Inc.	www.gfcn.org	n/a (contact form only)	(404) 494-7823	One West Court Square, Suite 750 Decatur, GA 30030
		Hawaii		
Hawai'i Primary Care Association	www.hawaiipca.net	n/a (contact form only)	(808) 536-8442	735 Bishop Street, Suite 230 Honolulu, HI 96813
		Idaho		
Idaho Primary Care Association	www.idahopca.org	info@idahopca.org	(208) 345-2335	1087 W River Street, Suite 160 Boise, ID 83702

Organization	URL	Contact Email	Phone Number	Address
		Illinois		
Illinois Association of Free and Charitable Clinics	www.illinoisfree Clinics.org	info@illinoisfree Clinics.org	(312) 863-1780	318 Walnut Street Charles, IL 60174
Illinois Primary Health Care Association	www.iphca.org/ Home.aspx	n/a (contact form only)	n/a (contact form only)	Springfield: 500 S. Ninth Street Springfield, IL 62701Chicago: 542 S. Dearborn Street, Suite 300 Chicago, IL 60605
		Indiana		
Indiana Primary Health Care Association	www.indianapca. org	info@indiana pca.org	(317) 630-0845	429 N. Pennsylvania Street, Suite 333 Indianapolis, IN 46204
		lowa		
Free Clinics of Iowa	www.freeClinicsof iowa.org	info@freeClinics ofiowa.org	(515) 954-7508	P.O. Box 12099 Des Moines, IA 50312
		Kansas		
Kansas Association for the Medically Underserved	www.kamuonline. org	http://www.kamu online.org/	(785) 233-8483	1129 S. Kansas Avenue, Suite B Topeka, KS 66612
		Kentucky		
Kentucky Association of Free & Charitable Clinics	http://www.kyafcc. org/	lebert12@ insightsbb.com	n/a	n/a
Kentucky Primary Care Association	www.kypca.net	n/a (contact form only)	(502) 227-4388 (502) 227-4379	226 West Main Street Frankfort, KY 40601
		Louisiana		
Louisiana Free Clinic Association	n/a	JAlcon@lchcc.net	(337) 593-9208	1317 Jefferson Street Lafayette, LA 70501
		Maine		
Maine Primary Care Association	http://mepca.org/	n/a	n/a	n/a
		Maryland		
Mid-Atlantic Association of Community Health Centers	www.machc.com/	info@machc.com	(301) 577-0097	4319 Forbes Boulevard Lanham, MD 20706
		Massachusetts		
Massachusetts League of Community Health Centers	www.massleague. org/	massleague @massleague.org	(617) 426-2225	40 Court Street, 10th Floor Boston, MA 02108

Organization	URL	Contact Email	Phone Number	Address
		Michigan		
Michigan Primary Care Association	www.mpca.net/	info@mpca.net	(517) 381-8000	7215 Westshire Drive Lansing, MI 48917
Free Clinics of Michigan	www.fcomi.org/	admin@fcomi.org	(269) 491-0493	1211 Lafayette Avenue NE Grand Rapids, MI 49505
		Minnesota		
Minnesota Association of Community Health Centers	www.mnachc.org/	n/a	(612) 253-4715	1113 East Franklin Avenue, Suite 202 Minneapolis, MN 55404
		Mississippi		
Mississippi Primary Health Care Association	www.mphca.com/	n/a	(601) 981-1817	6400 Lakeover Road, Suite A Jackson, Mississippi 39213
		Missouri		
Missouri Primary Care Association	www.mo-pca.org/	n/a (contact form only)	(573) 636-4222	3325 Emerald Lane Jefferson City, MO 65109
		Montana		
Montana Primary Care Association	www.mtpca.org/	Isalazar@mtpca.org	(406) 442-2750	1805 Euclid Avenue Helena, MT 59601
		Nebraska		
Health Center Association of Nebraska	http://hcanebraska. org/	info@HCA Nebraska.org	(402) 505-5426	3929 S. 147th Street Altech Plaza, Suite 100A Omaha, NE 68144-5529
		Nevada		
Nevada Primary Care Association	www.gbpca.org/	info@gbpca.org	(775) 887-0417	755 N. Roop Street, Suite 211 Carson City, NV 89701
		New Hampshire		
New Hampshire Office, Bi-State Primary Care Association	www. bistatepca.org/	n/a	(603) 228-2830	525 Clinton Street Bow, NH 03304
		New Jersey		
New Jersey Primary Care Association	www.njpca.org/	n/a	(609) 689-9930	3836 Quakerbridge Road, Suite 201 Hamilton, NJ 08619

Organization	URL	Contact Email	Phone Number	Address
		New Mexico		
New Mexico Primary Care Association	www.nmpca.org/	n/a	(505) 880-8882	4206 Louisiana NE Albuquerque, NM 87109
		New York		
New York Regional Association of Free Clinics	http://nysfree Clinics.org/index. html	contact@nysfree Clinics.org	n/a	n/a
Community Health Care Association of New York State	www.chcanys.org/	rherreros@ chcanys.org	(212) 279-9686	111 Broadway, Suite 1402 New York, NY 10006
		North Carolina		
North Carolina Association of Free Clinics	www.ncfree Clinics.org/	info@ncfree Clinics.org	(336) 251-1111	240 Tucker Avenue Winston-Salem, NC 27103
North Carolina Community Health Center Association	www.ncchca.org/	n/a (contact form only)	(919) 469-5701	4917 Waters Edge Drive, Suite 165 Raleigh, NC 27606-2459
		North Dakota		
North Dakota Office, Community Health Care Association of the Dakotas	www.community healthcare.net/	n/a (contact form only)	(701) 221-9824	1003 East Interstate Avenue, Suite 1, Bismarck, ND 58503
		Ohio		
Ohio Association of Free Clinics	www.ohiofree Clinics.org/	info@ohio freeClinics.org	(614) 545-0760	37 W. Broad Street, Suite 350 Columbus, OH 43215
Ohio Association of Community Health Centers	http://ohiochc.org/	info@ohiochc.org	(614) 884-3101	4150 Indianola Avenue Columbus, OH 43214
		Oklahoma		
Oklahoma Primary Care Association	https://okpca. publishpath.com/	n/a	(405) 424-2282	4300 N Lincoln Boulevard, Suite 203 Oklahoma City, OK 73105
Oklahoma Charitable Clinic Association	http://okcharitable clinics.org	n/a	(405) 607-4771	P.O. Box 54346 Oklahoma City, OK 73154

Organization	URL	Contact Email	Phone Number	Address
		Oregon		
Oregon Primary Care Association	www.orpca.org/	info@orpca.org	(503) 228-8852	310 SW 4th Avenue, Suite 200 Portland, OR 97204
		Pennsylvania		
Free Clinic Association of Pennsylvania	www.freeClinics pa.org/	mrivello@free Clinicspa.org	(610) 350-8122	980 East Penn Drive West Chester, PA 19380
Pennsylvania Association of Community Health Centers	www.pachc.com/	pachc@pachc.org	(717) 761-6443	1036 Mumma Road, Suite 1 Wormleysburg, PA 17043-1159
		Rhode Island		
Rhode Island Health Center Association	www.rihca.org/	info@rihca.org	(401) 274-1771	235 Promenade Street, Suite 455 Providence, RI 02908
		South Carolina		
South Carolina Primary Health Care Association	www. scphca.org/	n/a (contact form only)	(803) 788-2778	3 Technology Circle Columbia, SC 292023
South Carolina Free Clinic Association	www.scfree Clinics.org/	n/a	(864) 743-6003	525 N. Trenholm Road Columbia, SC 29206-1601
		South Dakota		
South Dakota Office, Community Health Care Association of the Dakotas	www.community healthcare.net/	n/a (contact form only)	(605) 357-1515	1400 West 22nd Street Sioux Falls, SD 57105
		Tennessee		
Tennessee Primary Care Association	www.tnpca.org/	n/a	(615) 329-3836	710 Spence Lane Nash- ville, TN 37217
		Texas		
Lone Star Association of Charitable Clinics	www.tx-lsacc.org/	jhopkins@tx-lsacc. org	(512) 777-8929	P.O. Box 684127 Austin, TX 78768
Texas Association of Community Health Centers	www.tachc.org/	n/a (contact form only)	(512) 329-5959	5900 Southwest Parkway Building 3 Austin, TX 78735

Organization	URL	Contact Email	Phone Number	Address		
	Utah					
Association for Utah Community Health	www.auch.org/	n/a	(801) 974-5522	860 East 4500 South, Suite 206 Salt Lake City, UT 84107		
		Vermont				
Vermont Coalition of Clinics for the Uninsured	www.vccu.net/	vccu@comcast.net	(802) 732-8253	PO Box 655 Bellows Falls, VT 05101		
		Virginia				
Virginia Community Healthcare Association	http://www. vacommunity- health.org/	marketing@vcha.us	(804) 237-7677	3831 Westerre Parkway Henrico, VA 23233-1330		
Virginia Association of Free and Charitable Clinics	www.vafreeClin-ics.org/	info@vafreeClinics. org	(804) 340-3434	1801 Libbie Avenue, Suite 104 Richmond, VA 23226		
		Washington				
Washington Association of Community & Migrant Health Centers	www.wacmhc.org/	staff@wacmhc.org	(360) 786.9722	510 Plum Street SE, Suite 101 Olympia WA 98501		
Washington Healthcare Access Alliance	www.wahealthcare accessalliance.org/	n/a (contact form only)	(267) 713-9422	P.O. Box 14506 Seattle, WA 98114		
		West Virginia				
West Virginia Primary Care Association	www.wvpca.org/	info@wvpca.org	(1-877) 982- 4584	1700 MacCorkle Avenue SE, One South Charles- ton, WV 25314-1518		
West Virginia Association of Free Clinics	www.wvafc.org/	prpope@wvafc.org	(304) 414-5941	1520 Washington Street East Charleston, WV 25311		
		Wisconsin				
Wisconsin Primary Health Care Association	www.wphca.org/	n/a (contact form only)	(608) 277-7477	5202 Eastpark Boulevard, Suite 109 Madison, WI 53718-8337		
Forward Health, Wisconsin Department of Health Services	www.dhs.wiscon sin.gov/forward- health/Clinics.htm	DHSwebmaster@ wisconsin.gov	(608) 266-1865	1 West Wilson Street Madison, WI 53703		
		Wyoming				
Wyoming Primary Care Association	www.wypca.org	wypca@wypca.org	(307) 632-5743	1720 Carey Avenue, Suite 601 Cheyenne, WY 82001		

Organization	URL	Contact Email	Phone Number	Address
		Regional Resources		
Northwest Regional Primary Care Association: Alaska, Oregon, Idaho, and Washington	www.nwrpca.org/ member-directory. html	info@nwrpca.org	(206) 783-3004	6512-23rd Avenue Northwest, Suite 305 Seattle, WA 98117
Free Clinics of the Western Region: Arizona, California, Colorado, Idaho, New Mexico, Nevada, Oregon, Utah, Washington, Wyoming	http://www. freeclinicswest.org/	Clinics@Free ClinicsWest.org	(619) 980-8128	2801 B Street, # 28 San Diego, CA 92102
Free Clinics of the Great Lakes Region	www.fcglr.org/	n/a	(207) 621-0677	73 Winthrop Street Augusta, ME 04330
		National Resources		
Free-Clinics.com	http://free-Clinics. com/	n/a	n/a	n/a
Health resources and Services Administration	http://findahealth center.hrsa.gov/ Search_HCC.aspx	ask@hrsa.gov	(888) 275-4772	5600 Fishers Lane Rock- ville, MD 20857
The National Association of Free & Charitable Clinics	www.nafc Clinics. org/	Info@nafc Clinics.org	(703) 647-7427	1800 Diagonal Road, Suite 600 Alexandria, VA 22314
Free Clinic Directory	http://freeClinic directory.org/	n/a (contact form only)	n/a	n/a
Free-HealthCare.com	www.hosted inc.net/fhc/index. html	n/a	(1-573) 996- 3333	P. O. Box 125 Doniphan, MO 63935-0125

APPENDICES Sample Forms

Appendix A:	Clinic Bylaws	A1
Appendix B:	Employee Manual	B1
Appendix C:	Harassment Policy	C
Appendix D:	Executive Director Job Description.	D
Appendix E:	Nurse Job Description	E1
Appendix F:	Model COBRA Continuation of Coverage ⁺	F1
Appendix G:	Collaborative Practice Agreement*	G
Appendix H:	Comparison of Free & Charitable Clinics to Federally Funded Clinics	H
Appenxid I: [Oonation Flyer	11

An excellent collection of State Specific Infographics is provided by the National Association of Free and Charitable Clinics at http://www.nafcclinics.org/resources/infographic. Each State's Infographic provides statistics on uninsured state residents and percentage of services offered by Free Clinics within that state.

- ⁺ Taken from the U.S. Department of Labor at http://www.dol.gov/ebsa/cobra.html.
- * Based on an agreement used by Louisiana State University's School of Nursing.

APPENDIX A Clinic Bylaws

Bylaws of the [Clinic's Name]

These Bylaws (referred to as the "Bylaws") govern the affairs of the [CLINIC], a non-profit corporation (referred to as the "Corporation").

Article 1

Offices

1.01. The principal office of the Corporation in the State of _____ shall be located in ____. The Corporation may have such other offices, either in [STATE] or elsewhere, as the Board of Directors may determine. The Board of Directors may change the location of any office of the Corporation. The Corporation shall comply with the requirements of the Act and maintain a registered office and registered agent in [STATE]. The registered office may, but need not, be identical with the Corporation's principal office in [STATE].

Mission

1.02 [CLINIC] exists to [INSERT MISSION STATEMENT].

Article 2

Board of Directors

Management of the Corporation

2.01. The affairs of the Corporation shall be managed by the Board of Directors.

Number, Qualifications, and Tenure of Directors

2.02. The number of directors shall be no less than three (3) directors, but no more than thirteen (13) directors. Directors need not be residents of the state of [STATE]. Each director shall serve for a term of three (3) years, with no director serving more than three (3) consecutive terms.

Election of Directors

2.03. Directors shall be elected by the majority of the Board of Directors. Each director shall hold office until a successor is elected and qualified.

Vacancies

2.04. Any vacancy occurring in the Board of Directors, and any director position to be filled due to an increase in the number of directors, shall be filled by the Board of Directors. A vacancy is filled by the affirmative vote of a majority of the remaining directors, even if it is less than a quorum of the Board of Directors, or if it is a sole remaining director. A director elected to fill a vacancy shall be elected for the unexpired term of the predecessor in office.

Regular Meetings

2.05. The regular meetings will be the third Thursday of each month. The meetings may be held either within or without the State of _____. Meetings may be cancelled by vote of the Board of Directors.

Special Meetings

2.06. Special meetings of the Board of Directors may be called by or at the request of the president or any two directors with the approval of the executive committee or the executive director. Notice of any special meeting of the Board of Directors shall be delivered to each director not less than seventy-two (72) hours before the date of the meeting. The notice shall state the place, day, and time of the meeting, who called the meeting, and the purpose or purposes for which the meeting is called.

Quorum

2.07. A majority of the number of directors then in office shall constitute a quorum for the transaction of business at any meeting of the Board of Directors.

Duties of Directors

2.08. Directors shall discharge their duties, including any duties as committee members, in good faith, with ordinary care, and in a manner they reasonably believe to be in the best interest of the Corporation.

Delegation of Duties

2.09. Directors are entitled to select advisors and delegate duties and responsibilities to them, such as the full power and authority to purchase or otherwise acquire stocks, bonds, securities, and other investments on behalf of the Corporation; and to sell, transfer, or otherwise dispose of the Corporation's assets and properties at a time and for a consideration that the advisor deems appropriate. The directors have no liability for actions taken or omitted by the advisor if the Board of Directors acts in good faith and with ordinary care in selecting the advisor.

Interested Directors

2.10. Contracts or transactions between directors or officers who have a financial interest in the matter are not void or voidable solely for that reason. No director shall participate in any transaction if such transaction would constitute an act of self-dealing as defined in Internal Revenue Code Section 4941 and the regulations and ruling promulgated thereunder.

Actions of Board of Directors

2.11. The vote of a majority of directors present in person and voting at a meeting at which a quorum is present shall be sufficient to constitute the act of the Board of Directors unless the act of a greater number is required by law or the Bylaws.

Compensation

2.12. Directors shall not receive compensation for their services; however, each director may be entitled to reimbursement for expenses incurred in their services with the approval of the Board of Directors.

Removal of Directors

2.13. A director may be removed form office for failure to perform his duties by the affirmative vote of a majority of the Board of Directors.

Article 3

Officers

Officer Positions

3.01. The officers of the Corporation shall be a president, a secretary, a treasurer, and one vice president, who will make up the executive committee.

Election and Term of Office

3.02. The officers of the Corporation shall be elected annually by the Board of Directors at the regular May meeting of the Board of Directors, or as soon thereafter as conveniently possible. Each officer shall hold office until a successor is duly selected and qualified.

Vacancies

3.03. A vacancy in any office may be filled by the Board of Directors.

President

3.04. The president shall preside at all Board of Directors meetings and shall perform other duties as prescribed by the Board of Directors.

Vice President

3.05. When the president is absent or unable to act, the vice president shall perform the duties of the president. A vice president shall perform other duties as assigned by the president or Board of Directors.

Treasurer

3.06. The treasurer shall:

- (a) Have charge and custody of and be responsible for funds and securities of the Corporation.
- (b) Provide oversight over the financial books and records of the Corporation and monthly financial reports.
- (c) Perform other duties as assigned by the president or by the Board of Directors.

Secretary

3.07. The Secretary shall:

- (a) Give all notices as provided in the Bylaws and as required by law.
- (b) Take minutes of the meetings of the Board of Directors, keep the minutes as part of the corporate records, and send copies of the minutes of each Board of Directors meeting to all directors.
- (c) Keep a register of the mailing address of each director of the Corporation.
- (d) Perform duties as assigned by the Board of Directors.

Article 4

Committees

Establishment of Committees

4.01. The Board of Directors may adopt a resolution establishing one or more committees, delegating specified authority to a committee, and appointing or removing members of a committee. The establishment of a committee or the delegation of authority to it shall not relieve the Board of Directors, or any individual director, of any responsibility imposed by the Bylaws or otherwise imposed by law. No committee shall have the authority to amend or repeal these Bylaws, elect or remove any officer or director, adopt a plan of merger, or authorize the voluntary dissolution of the corporation.

4.02. Executive Committee. There shall be an Executive Committee composed of the President, Vice President, Treasurer, Secretary, and the immediate Past President. The President is Chair of this committee. A majority of the members of the Executive Committee shall constitute a quorum. The Executive Committee shall periodically review and make recommendation to the Board and shall exercise when the Board is not in session, all powers which

the Board may lawfully delegate. Generally, all major functions of the Corporation shall be subject to review by the Executive Committee. Actions taken by the Executive Committee will be presented to the full Board for review at the next meeting of the Board.

Rules

4.03. Each committee may adopt rules for its own operation not inconsistent with the Bylaws or with the rules adopted by the Board of Directors.

Article 5

Transactions of the Corporation

Contracts

5.01. The Board of Directors may authorize any officer or agent of the Corporation to enter into a contract or execute and deliver any instrument in the name of and on behalf of the Corporation.

Deposits

5.02. All funds of the corporation shall be deposited to the credit of the corporation in banks, trust companies, or other financial institutions or depositories that the Board of Directors selects.

Potential Conflict of Interests

5.03. The Corporation shall not make any loan to a director of the corporation or any other "disqualified person" as that term is defined in Internal Revenue Code Section 4946 (a) and the regulations and rulings promulgated thereunder. A director, officer, or committee member of the Corporation may lend money to and otherwise transact business with the Corporation except as otherwise provided by the Bylaws, articles of incorporation, and all applicable laws and then only to the extent any such loan or transaction does not constitute an act of self-dealing as defined in Internal Revenue Code Section 4941 and the regulations and rulings promulgated thereunder. The Corporation shall not borrow money from or otherwise transact business with a director, officer, or committee member of the Corporation unless the transaction is described fully in a legally binding instrument and is in the best interest of the Corporation. The Corporation shall not borrow money from or otherwise transact business with a director, officer, or committee member of the Corporation without full disclosure of all relevant facts and without the approval of the Board of Directors, not including the vote of any person having a personal interest in the transaction.

Article 6

Books and Records

Required Books and Records

The Corporation shall keep correct and complete books and records of account in compliance with the Corporation's Record Retention Policy.

Article 7

Fiscal Year

The fiscal year of the Corporation shall be from July 1st through June 30th of the following year.

Article 8

Indemnification

When Indemnification is Required, Permitted, and Prohibited

Unless otherwise prohibited by law, the Corporation may indemnify any director or officer or any former director or officer, and may by resolution of the Board of Directors indemnify any employee, against any and all expenses and liabilities incurred by him or her in connection with any claim, action, suit, or proceeding to which he or she is made a party by reason of being a director, officer, or employee. However, there shall be no indemnification in relation to matters as to which he or she shall be adjudged to be guilty of a criminal offense or liable to the Corporation for damages arising out of his or her own gross negligence in the performance of a duty to the Corporation.

Article 9

Amendments to Bylaws

These Bylaws may be amended or new Bylaws adopted upon the affirmative vote of twothirds of all the directors then in office at any regular or special meeting of the Board of Directors. The notice of the meeting shall set forth a summary of the proposed amendments.

APPENDIX B Employee Manual

Employee Manual

Letter from Executive Director

[To be provided by the Executive Director]

Mission

The mission of the CLINIC NAME is to promote health and wellness by providing quality services, at no charge, to people without access to basic health care. We accomplish this by:

- Respecting the dignity of each individual;
- Serving a diverse community;
- Providing outreach services within our community;
- Working collaboratively with volunteers;
- ♦ Fostering individual and community partnerships;
- A Responding to the changing health and wellness needs of the community;
- Maximizing our financial resources.

Vision

Creating a solution for a healthy community.

Our Values

1. Respecting the Dignity of Each Individual

Each client, patient, or visitor to the Clinic should be treated with the greatest level of respect and extended the utmost level of dignity in the care they seek.

2. Serve a Diverse Community

The Clinic, as a non-profit health and social service organization, operates in some of INSERT CITY NAME's most diverse communities. The Clinic strives to become culturally competent in the areas we serve and seeks to meet the health and wellness needs of the under and uninsured members of these communities.

3. Provide Outreach Services Within the Community

As part of the Clinic's health and prevention programs, outreach activities are essential to meeting the needs of these communities. One of the Clinics' main objectives is to educate the community on health and wellness.

4. Work Collaboratively with Volunteers

Since the Clinic's inception, volunteers have been a critical component to our growth and success as one of the premier health Clinics in INSERT CITY NAME. The Clinic values its volunteer staff and encourages staff to utilize volunteers as a Clinic resource.

5. Foster Individual and Community Partnerships

The Clinic views its ability to collaborate and build partnerships with other health and social services organization throughout the community as one of its greatest strengths. The CLINIC NAME views this as a way to maximize community resources in order to fulfill our mission.

6. Respond to the Changing Health and Wellness Needs of the Community The Clinic sees itself as an organization flexible enough to meet the ever changing and evolving health and wellness needs of the community. We seek meaningful consumer input and perform detailed program evaluation to adequately meet the communities changing needs.

7. Maximizing Financial Resources

The employees recognize the Clinic's limited financial resources and seek to leverage our existing resources and partnerships to be good stewards of the community resources that we are given.

TABLE OF CONTENTS

Letter from the Executive Director

Mission

Vision

Our Values

INTRODUCTION

EQUAL EMPLOYMENT OPPORTUNITY

EMPLOYMENT STATUS

At-Will Employement

Full-Time Employees

Part-Time Employees

Temporary/Seasonal Employees

PRN Employees

Exempt Employees

Non-Exempt Employees

Training Period

EMPLOYMENT PRACTICES

Restrictions on Employment

Job Descriptions

Work Hours and Breaks

Time Records

Pay-Days

Overtime Pay

Work Promotions and Transers

ENDING EMPLOYMENT

Voluntary Resignation

Involuntary Separation from Employment

Workforce Reduction

DEFINITION OF IMMEDIATE FAMILY

EMPLOYEE HEALTH MEASURES AND HEALTH RECORDS

Health Insurance Portability and Accountability Act (HIPAA)

EMPLOYEE ORIENTATION

FORMS AND RECORDS

Personnel Records

WORK SITE ASSIGNMENTS

LEAVE

Designated Holidays

Religious Holidays

Vacation

Sick Leave

Attendance

Excused/Unexcused Absence

Family Medical Leave

Bereavement Leave

Inclement Weather

Legal Obligations

Military Leave

EMPLOYEE BENEFITS

Mandatory Benefits

Voluntary Benefits

HIPAA as it Relates to Benefits

ERISA

WORK SUPERVISION AND PERFORMANCE EVALUATION

Chain of Command

Performance Evaluations

Open Door Policy

STANDARDS OF CONDUCT

Clinic HIPAA Regulations and Confidentiality of Patient and Client Information

Prohibition of Harassment and Discrimination

Tobacco

Alcohol and Drug Free Workplaces

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Rehabilitation Leave

Prohibition of Firearms

Workplace Environment

Violence in the Workplace

Clinic Property

The Media

Gifts and Rebates

Patient and Client Transportation

Use of Telephone, Electronic Mail, and Internet Systems

Prohibition of Political Activity

Personal Appearance Guidelines

Conduct Summarization

ETHICS POLICY

Code of Ethics

Conflict of Interest

INCIDENTS, ACCIDENTS, AND INJURIES

EMPLOYEE GRIEVANCES

Grievance Process

Appeal Process

Alternative Process

EMPLOYEE TRAVEL

Ground Transportation

Air Travel

Parking Fees

Fines

Lodging

Meals

Travel Advances

CONTINUING EDUCATION

Required

Voluntary

ISSUES NOT SPECIFICALLY COVERED IN THIS HANDBOOK

EMPLOYEE ACKNOWLEDGMENT FORM INTRODUCTION

A key organizational goal for the [INSERT CLINIC NAME], as found in the strategic plan, is to provide a personally and professionally rewarding work environment. In pursuit of this goal the Board of Directors has adopted the following policies contained in this handbook. These policies, which are subject to periodic review, change and amendment, are designed to create a workplace environment where each employee is able to contribute to fulfilling the Clinic's mission. Please keep this book so that you may easily access the information in it.

The handbook also sets forth the [INSERT CLINIC NAME] (here after referred to as "the Clinic") benefits and expectations for staff. Circumstances may arise in which the Clinic may change polices and guidelines set forth in this handbook, therefore the Clinic reserves the right to revise, supplement, or rescind any policies or portion of the handbook or take any actions that may be contrary to a guideline or procedure, from time to time as the Clinic deems appropriate, in its sole and absolute discretion with or without notice. Such revisions shall be only as approved by the Executive Director and shall be communicated with employees as it may be required.

This handbook is not intended as, or sets forth as any contractual agreements, obligations or commitments by the Clinic to any individual or group of employees and no staff member has any contractual right to the matters contained herein. Employment with the Clinic is "at will" and may be terminated by the employee or by the Clinic at any time with or without notice. Because it is not possible to cover all situations that may arise, any questions that you may have regarding wages, benefits, or other policies or practices should first be directed to your immediate supervisor.

EQUAL EMPLOYMENT OPPORTUNITY

Opportunities are provided to all employees and applicants for employment free of unlawful discrimination. This includes, but is not limited to, recruitment, hiring, training, promotion, compensation, benefits and all other terms and conditions of employment, provided the individual is qualified and able to perform the work available. The Clinic's Affirmative Action Program is intended and utilized to increase participation of women, minorities, persons with disabilities, persons over 40 years of age and/or veterans, where they are underutilized. The Human Resources Manager is the Clinic's Equal Employment Opportunity (Affirmative Action) Officer and any questions or comments regarding the Clinic's Affirmative Action plan should be directed to this position.

Notwithstanding the protection offered by all applicable federal, state and local laws, any employee who feels this policy has been violated has the right to report such concerns according to the procedures established in the **Employee Grievance** section of this handbook.

EMPLOYMENT STATUS

At-Will Employment

The Clinic is an "at will" employer, meaning the employee or employer may end employment at any time with or without notice. No statements whether oral or written made in any of the Clinic's policies, practices, procedures or guidelines will alter the "at-will" employer employee relationship.

All employees should understand that their position is supported by government or private grants, and that continued employment is subject to funding or reauthorization by a legislative body or board outside the direct control of this agency. Therefore, employment may end if funding is reduced or eliminated.

Full-Time Employees

Full-Time Employees, who regularly work thirty-two (32) hours or more per week, are eligible to participate in the entire employee benefits described in the Employee Benefits section of this Handbook.

Part-Time Employees

Part-Time Employees, who regularly work less than thirty-two (32) hours a week, are eligible to receive paid time off only as outlined in the **Leave** Section of this Handbook.

Temporary/Seasonal Employees

Temporary/Seasonal employees are individuals hired directly by the Clinic whose work assignment is expected to be of limited duration, (as opposed to being contracted through a temporary employment agency) to work during peak periods, to engage in special assignments or projects or to fill-in for employees who must be absent from work. As a general rule management expects a temporary/seasonal position to discontinue at a certain future time. Temporary/Seasonal employees may be hired to work any type of work schedule. Regardless of the number of hours worked they are only eligible to receive holiday paid time off and are not eligible to participate in the Clinic's employee benefits package.

PRN Employees

PRN employees are individuals whose work assignment is on an as needed basis to work during peak periods, to engage in special assignments or projects or to fill-in for employees who must be absent from work. PRN positions are not on a regular schedule but are flexible to work when called. PRN employees are not eligible to receive any paid time off and are not eligible to participate in the Clinic's employee benefits package.

Exempt Employees

Exempt employees are individuals hired to fill positions that meet the criteria of executive, administrative, or professional as defined in the Fair Labor Standards Act. Exempt employees are exempt from overtime. Overtime wage provisions of the Fair Labor Standards Act do not apply to them.

Non-Exempt Employees

Non-exempt employees are hired to fill positions that do not meet the criteria of executive, administrative, or professional employee as defined in the Fair Labor Standards Act. The overtime wage provisions of the Fair Labor Standards Act do apply to non-exempt employees and therefore they are paid wages at one and one half times (1 ½) their regular hourly rate for any actual hours worked in excess of 40 hours in a work week. The Clinic reserves the right to reclassify positions with regard to exempt and non-exempt status whenever necessary.

Training Period

The training period is defined as the first six (6) calendar months from the first day of employment for a newly hired employee. It is recommended that near the end of the training period, the supervisor and new employee have a conference to evaluate the employees' performance, adjust expectations and revisit goals. An employee's successful completion of the training period does not guarantee continued employment with the Clinic.

Any employee who transfers into another position (a position with a different Job Description) will be considered in a three (3) calendar month training period in the new position. However, for purposes of participation in all employee benefits etc., such employees' service at the Clinic will be counted from their original date of hire.

EMPLOYMENT PRACTICES

Restrictions on Employment

Employees may not serve as a member of the Clinic's Board of Directors. A family member of a current employee, including in-laws and cousins or anyone who meets the definition of **Immediate Family** as defined in this handbook may not be employed at the Clinic.

Full-time employee may not "moonlight" or be employed by another entity while employed at the Clinic without the permission of their immediate supervisor and the Executive Director. Clinic employees may act as outside consultants to other agencies, groups or institutions with the approval of the Executive Director. The employee can retain fees for such consultations if performed during vacation time, outside of normal operating hours and are not a part of the employee's Clinic responsibilities. For consulting performed during regular working hours, or on behalf of the Clinic, any fees must be paid directly to the Clinic.

Job Descriptions

Every employee will receive a written Job Description for the position they occupy. The Job Description will include the position's title, classification (i.e., exempt/non-exempt), a general description of the position, a list of the position's essential functions, the skills and qualifications required for the position, and the position's supervisor. All Job Descriptions should be signed and dated by the employee. Job Descriptions do not constitute an employment contract.

Work Hours and Breaks

The standard workweek is considered 37.5 hours of work per week. All employees are expected to take a paid thirty (30)-minute meal break and are allowed two paid fifteen (15)-minute breaks whenever the workload allows. Breaks are limited to the prescribed length and may not interfere with the orderly operation and productivity of the Clinic services and may not be used in conjunction with another break. All other breaks in excess of twenty (20) minutes or longer, must be deducted from the employees' recorded time. Excessive and unauthorized breaks may be subject to corrective action up to and including separation from employment. The employee's immediate supervisor must approve all lunch and break schedules and work hours. Assumption of a duty or assignment from another employee without authorization from the supervisor in charge is not permitted. In addition to the regular work hours, certain employees may be required to be available on an "on call" basis (accessible by pager and/or telephone) as needed by Clinic management.

Time Records

Accurately recording time worked is the responsibility of every non-exempt employee. Federal and state laws require the Clinic to keep an accurate record of all time worked in order to calculate employee pay and benefits. Time worked is all the time actually spent on the job performing assigned duties. Non-exempt or hourly employees are required to record their time **each day** on their Employee Time Tracking form (time sheet) and must accurately record the time they begin and end their work. They must also accurately record the beginning and ending time of any split shift or departure from work for personal reasons. All employees, exempt and non-exempt, are required to note on their time sheets exceptions from the normal schedule such as holidays, vacation days and sick days.

The Clinic expects employees to record all time worked and all used paid time off in an accurate and honest manner. It is the employee's responsibility to sign their time record to certify by penalty of perjury by law the accuracy of all time recorded. Supervisors must approve all time recorded prior to submitting time records to payroll. In addition, if corrections or modifications must be made to the time record, the employee and supervisor must verify the accuracy of the change(s). Altering, falsifying, or tampering with time records, or

recording time on another employee's time record, may result in corrective action up to and including separation from employment.

Pay-Days

Paychecks will be issued on the fifteenth (pay period: 25th day of the previous month to the 9th of the current month) and last working day of the month (pay period: 10th through the 24th). If the regularly scheduled payday falls on a weekend, paychecks will be issued on Friday before. If the regularly scheduled payday falls on a holiday, paychecks will be issued on the last working day preceding the holiday. All employees are **strongly encouraged** to use direct deposit. The Clinic does not advance pay to any employee.

It is the employees' responsibility to present an accurate record of time to their supervisor prior to payroll being calculated. If not submitted in a timely manner it may result in the delay of a paycheck.

Overtime Pay

Overtime pay is calculated for non-exempt hourly employees based on one and one half times (1½) their regular hourly rate. As required by law, overtime is calculated based on actual hours worked over 40 hours per regular work week. A regular work week is Monday at 12:00 am through the following Sunday at 11:59 pm. Time off on sick leave, vacation or any other leave of absence will not be considered hours worked for the purposes of calculating overtime.

All overtime hours must be pre-approved by the employees' immediate supervisor. Employees engaging in unauthorized overtime may be subject to corrective action up to and including separation from employment.

Work Promotions and Transfers

As a general rule, the Clinic will seek to fill vacant positions through a competitive application process. Whenever possible, qualified persons currently employed at the Clinic will be given the opportunity to apply for a vacant position when it is advertised. Employees should keep in mind that the Clinic must fill its vacant positions with the most qualified candidates available; therefore, by itself, current employment at the Clinic does not guarantee work promotions or transfers.

ENDING EMPLOYMENT

Ending employment is an inevitable part of any job with any organization. The policies, practices and procedures discussed herein are not intended to form a contract between the Clinic and any employee. A departing employee must return to their immediate supervisor

all Clinic property in their possession. This may include keys, credit cards, books, all documents owned by the Clinic, employee time reports, expense reports, statistical reports, all passwords for the computer and phone system, etc.

Notice compensation is at the sole discretion of the Clinic; however it will not be paid when separation from employment is for misconduct. Examples of misconduct may include, but are not limited to, any infraction of policies, guidelines, procedures and practices as set forth in this handbook, any infractions of department or program policies, guidelines, procedures and practices.

The Clinic recognizes that each separation from employment situation presents a unique set of circumstances, below are some common examples under which employment may end and the Clinic's policies regarding each:

Voluntary Resignation

A separation from employment of employment voluntarily initiated by the employee should be submitted in writing to the employee's immediate supervisor. The immediate supervisor or a Director is responsible for communicating the resignation to the staff.

In order to minimize disruptions of patient and client care, a resigning employee is requested to notify their immediate supervisor of their effective resignation date as far in advance as possible. Non-director level employees are expected to give a minimum notice of two (2) weeks. Director and manager level employees are expected to give a minimum notice of thirty (30) days. An employee who fails to provide sufficient notice may not be eligible for rehire and will forfeit any vacation balance accrued. The Clinic reserves the right to waive notice. Also at the time of resignation the employee is no longer eligible to use sick leave and the supervisor may request the employee take unused vacation earned prior to the resignation effective date.

Payment for wages earned and accrued but unused vacation will be paid according to the scheduled pay dates. Accrued but unused sick will not be paid. Benefits end on the last day of the month that the separation from employment is effective.

Involuntary Separation of Employment

While it is the Clinic's goal to resolve any issues or differences that may arise, it is not always possible to do so. The Clinic is an "at will" employer and may terminate the employer employee relationship at any time for any reason with or without notice.

When separation from employment is involuntary, employees will be paid all earned wages according to the scheduled pay dates. They may receive accrued but unused vacation except when separation from employment is for misconduct.

Workforce Reduction

There may be times when, due to economic factors, a position's hours may have to be reduced or completely eliminated. The economic factors necessitating a reduction in the workforce generally include but are not limited to, partial or complete loss of a specific grant, reduced patient and client demand for a particular service, chronic patient and client under-utilization of a non-essential service, and general organizational restructuring or downsizing.

The Clinic's management will make every effort to ensure that decisions regarding workforce reductions are not arbitrary and, whenever possible, are supported by objective data, e.g., notice of funding reduction/elimination, documented steady decline in a service's utilization, documented chronic under-utilization of a non-essential service, or a change in functions are needed.

When possible, employees affected by a reduction in workforce will be provided prior notice. Employees separated through reduction in workforce will receive wages and accrued but unused vacation according to the scheduled pay dates.

DEFINITION OF IMMEDIATE FAMILY

For the purposes of Personnel Policies, where it is not otherwise defined by applicable law or regulation, the Clinic considers the following to be members of an employee's immediate family: spouse or domestic partner (regardless of gender); children (birth, adopted and foster children); parents, spouse's or domestic partners parent (including adoptive parents, foster parents, or grandparents acting in the place of parents); siblings; and other persons (whether biologically related to the employee or not) for whom the employee can demonstrate that they bear primary domestic care-giving responsibilities.

EMPLOYEE HEALTH MEASURES AND HEALTH RECORDS

Federal and State regulations require the Clinic maintain certain health records on all employees. These records are maintained by the Human Resources Department and are kept separate from personnel files. All employees must comply with health measures including tests, screenings, vaccinations and precautions as outlined in the Clinic's Infection Control Polices. These measures are offered to you, as a Clinic employee, in order to provide a safe and effective work environment. Employees may discuss required and recommended measures with the employee health nurse.

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The Clinic is compliant with rules and regulations regarding the Federal HIPAA legislation. Employees have the right to protection and privacy of their employee health records as do clients and patients. The employee health records are kept separate from the employee's personnel record with limited access by appropriate and Human Resources staff.

EMPLOYEE ORIENTATION

The immediate supervisor is responsible for introducing the new employee to the rest of the Clinic staff and for conducting a tour of the Clinic's facilities. During orientation a new employee will not be expected to have full responsibility for the duties listed in their Job Description. Instead, new employees will be assigned to follow and observe the customary activities of other staff members from throughout the Clinic. Employees in orientation should avoid making work-related decisions without first consulting their immediate supervisor and/or a senior staff member with whom they are assigned to work.

Time should be set-aside during orientation for new employees to read Clinic manuals and other pertinent or assigned literature. Any questions raised by reading the materials should be addressed to the immediate supervisor and/or other appropriate staff. New employees will receive written and verbal information on the topics such as the Clinic's history, vision, mission, core values, programs, organizational chart, benefits, safety and other materials pertinent to Clinic operations and employment.

FORMS AND RECORDS

All employees must complete the proper new hire paperwork within the first three (3) days of employment including but not limited to, federal and state W-4, federal I-9, etc. Employees must have an application for employment and any other forms and records that may be required in their personnel file. A person cannot be considered officially employed until these forms are properly completed.

Personnel Records

The Clinic maintains files on each employee. These files contain hiring and employment information deemed important by management.

Supervisors are responsible for making sure that all documents are submitted for filing in a timely manner. These documents may include a supervisor-employee counseling session, training attendance forms, continuing education records, licenses, certifications, performance evaluations and more.

An active employee may view or request a copy of any document entered in their personnel file by making a written request to Human Resources. HR will then make an appointment with the employee to view or receive copies as soon as it is feasibly possible. Persons, whose employment has been terminated for any reason, may not receive copies of any document in their personnel file except by an official subpoena.

All personnel files will be kept in a locked cabinet at all times, except for when a file is needed by authorized personnel for a specific reason. The locked cabinet will be kept in the main administrative offices. Only authorized administrative personnel will have access to the personnel file cabinet. All employee medical files will be kept separate from the personnel files.

The Clinic maintains sole property rights over all personnel and payroll files. Unless subpoenaed by an appropriate governing body with competent jurisdiction or unless required in the defense of a legal claim or charge, the information contained in personnel files will be maintained as confidential and will not be released to parties outside of the Clinic.

WORK SITE ASSIGNMENTS

Most employees will be assigned to a primary site where they will routinely report for work activities. However, from time to time employees may be assigned to a site other than their primary work site according to the Clinic's overall staffing needs. Work site assignments are determined by the immediate supervisor with the approval of the proper Director and are subject to change. It should be noted that visiting a patient's or client's home is an integral part of certain jobs. Employees whose job requires them to make home visits must not consider any individual patient or client home to be their primary work site.

It is recognized that work site assignments may give rise to safety concerns. Employees are encouraged to voice those concerns to their immediate supervisor. Supervisors must take those concerns seriously and, together with the employee and any other appropriate personnel, implement reasonable measures to increase the employee's level of confidence or assess what may be appropriate and the safety of the environment. However, an employee's blanket refusal to accept any assignment to a work site or a patient or client home will not be permitted. Any such blanket refusals may subject an employee to corrective action, up to and including separation from employment.

LEAVE

The following describes the types of leave the Clinic offers and the policies, practices and guidelines for each. If you have a question regarding leave you should discuss it with your immediate supervisor first.

Designated Holidays

The Clinic observes ten (10) work holidays per year. Those holidays are:

- New Year's Day (one day)
- ♦ Martin Luther King, Jr.'s Birthday (one day)
- Memorial Day (one day)
- ♦ Independence Day or Fourth of July (one day)
- ♦ Labor Day (one day)
- Thanksgiving (two days)
- Christmas (two days)
- One personal day or 'floating holiday' to be approved by your supervisor (Must be hired prior to October 1st to use in the same calendar year).

Most employees will be off work with pay on a day the Clinic observes as a holiday. However, some employees may be required to work on a designated holiday due to Clinic activities. Non-exempt employees who are required to work a holiday will be paid holiday pay at one and one-half times (1½) their regular hourly rate. An exempt employee who is required to work the holiday will be allowed to take a paid day off at a later scheduled time arranged through their supervisor. Part time Holiday pay will be pro-rated based on the number of hours the employee is hired to fulfill for example: employees hired for 5 hours a week will be paid 1 hours; 10 hours a week will be paid 2 hours; 20 hours a week will be paid 4 hours; 30 hours will be paid 5 hours for the holiday observed.

Religious Holidays

The Clinic respects the right of each employee to worship as their faith dictates, but for economic and patient, client service reasons the Clinic will not observe religious holidays other than Christmas. Employees are free to utilize personal days or vacation days toward other religious holidays they wish to observe. Please make arrangements with your supervisor at least two (2) weeks in advance or as far in advance as possible.

Vacation

Employees begin accruing vacation based on their hire date but become eligible to take vacation after completing a mandatory waiting period of six (6) consecutive months from their hire date. Vacation leave used prior to six (6) months must have previous approval by the employee's supervisor and the Executive Director. Accrued vacation time may be used provided two (2) weeks notice is given and as long as business needs allow. Requests made with less than two (2) weeks notice maybe granted at the discretion of the immediate supervisor.

Employees accrue vacation based on the vacation leave schedule below:

- ♦ 0-3 years of continuous service—2 working days per year
- 4th anniversary date-6 years of continuous service—15 working days per year
- ♦ 7th anniversary date+ years of continuous service—20 working days per year

Full time employees will accrue vacation hours per pay period. Part-time employees will accrue vacation hours on a pro-rated basis based on the number of hours worked.

An employee may accrue vacation leave to a maximum of one and one-half (1½) times the amount earned in one year. The Executive Director may extend the maximum accrual when it is determined that an employee cannot be allowed to take vacation leave due to a temporarily heavy work schedule. In certain individual situations the Executive Director may grant additional vacation time to an employee.

Sick Leave

Employees begin accruing sick leave based on their hire date but are eligible for sick leave following sixty (60) days of continuous employment. A supervisor may approve leave for a new employee within the first 60 days of employment; however that time may still be counted against the employee's attendance record. Any excessive leave may reflect negatively on an employee's attendance record and may lead to corrective action up to and including separation from employment.

Full time employees will accumulate sick leave hours per pay period. Part-time employees will accrue sick leave on a pro-rated basis based on the number of hours worked.

Unused sick leave may accumulate up to a maximum of sixty (60) working days. Sick leave may be taken in minimum increments of one (1) hour. It may be used for illness for

the employee or a member of the immediate family as defined in this handbook. Proper documentation from a physician may be required for any illness of three (3) days or more. Sick leave is not available to departing employees once notice has been given; nor will they be paid for any accrued unused balance.

Notification of sick leave should be made to the employee's direct supervisor a minimum of one hour prior to the shift worked unless an unforeseen emergency occurs in which case the supervisor must be made aware as soon as feasibly possible by the employee or by someone authorized to notify the employer on the employees' behalf.

Attendance

Employees are to report to work during the hours they are normally scheduled to work. If the employee fails to report to work during normal hours they will be considered absent.

Excused/Unexcused Absence

An excused absence is when an employee notifies their supervisor of an upcoming absence and receives acknowledgement and approval.

An unexcused absence is failure to notify the supervisor in advance of a non-emergency absence, failure to call one hour in advance of your shift or no notification is made. Unexcused or excessive absences are subject to corrective action up to and including separation from employment.

Absences for 3 days or more without any notification will be considered voluntary resignation.

Family Medical Leave

The Clinic complies with the requirements of the Family and Medical Leave Act of 1993 (FMLA). FMLA leave is unpaid leave of up to 12 weeks (480 hours) per 12 month period for the following reasons:

- ♦ For the birth and care of the newborn child of the employee;
- ♦ For placement with the employee of a son or daughter for adoption or foster care;
- ♦ To care for an immediate family member (spouse, child, or parent) with a serious health condition; or
- To take medical leave when the employee is unable to work because of a serious health condition.

Eligibility

To be eligible for leave, you must have been employed by the Clinic for at least twelve (12) months (which need not be consecutive) and have completed at least 1,250 hours of service during the twelve month period immediately preceding the commencement of the leave.

Notification Requirements

When the need for leave is foreseeable, such as the birth, adoption or placement of a child for adoption or foster care, or for planned medical treatment, the employee must provide thirty days (30) advance notice. When it is not practical under the circumstances to provide such advance notice, such notice must be given "as soon as practical," or ordinarily within two business days of when the employee learns of the need for the leave. When planning medical treatments, employees should consult with the Clinic when giving notice and make reasonable efforts to schedule the leave so as not to unduly disrupt the Clinic's operations. Notice to the Clinic should be given either in person or by telephone when medical emergencies are involved. Notice may be given by the employee's spouse or other family member if the employee is unable to do so due to a serious health condition. Failure to provide notice may delay leave for up to thirty (30) days. The Clinic may require periodic notice throughout the leave period.

Physician Certification

The employee is required to provide a physician's certification supporting the need for such leave due to a serious health condition affecting the employee or an immediate family member. This certification must be provided within fifteen (15) days of the request unless it is not practicable under the circumstances. Failure to provide certification may result in your leave being delayed, denied, or revoked.

The Clinic may require a second or third medical opinion at the employers' expense. The Clinic may require periodic recertification of the employee's status and intent to return to work.

Spouse

Spouses employed by the Clinic are jointly entitled to a combined total of 12 weeks to which both may take FMLA leave for the birth or placement of a child, or to care for a parent with a serious health condition, and are limited to twelve weeks during a twelve month period.

Intermittent Leave

Under certain circumstance employees may take FMLA leave intermittently or on a reduced leave schedule. If intermittent leave is due to birth or placement of a child then such use is subject to employers' approval. When intermittent leave is medically necessary, such leave

should be scheduled so as not to interfere with the Clinic's operations. In addition the Clinic may assign an employee to an alternative position with equivalent pay and benefits that better accommodate the employee's intermittent or reduced leave schedule.

Maintaining Benefits While on FMLA

During FMLA leave, the Clinic will maintain health insurance coverage on the same basis as if you were not on leave. The employee is fully responsible for all voluntary coverage. The Clinic may recover the full premium paid for maintaining coverage if the employee fails to return from leave, in accordance with FMLA. If the employees portion of coverage is more than thirty (30) days late, coverage may cease.

If paid leave is available, then payments for coverage will be made through payroll deduction. For any portion of leave that is unpaid, then the employee is responsible to make payments to the Clinic by the 5th of the month or coverage may lapse or cease.

Paid and Unpaid Time Off

All accrued but unused time will be paid concurrent with FMLA leave. This includes sick, vacation, and personal holiday time. Once all paid time off is exhausted, the remainder of FMLA leave is unpaid.

Return to Work

When returning to work after FMLA leave, you will be placed in your original job or an equivalent job with equivalent pay, benefits, duties, responsibility, and authority. You will not lose seniority or other benefits accumulated prior to FMLA leave.

Upon returning to work after an employee's own serious health condition, the employee must provide a proper "return to work report" from the attending physician.

Once leave is exhausted and the employee fails to return to work for reasons not eligible for continuation under FMLA, the Clinic is no longer obligated to continue employment.

Fraudulent Leave

The Clinic reserves the right to take action, up to and including separation from employment for fraudulently obtaining FMLA Leave.

Bereavement Leave

In order to facilitate an employee's grief and bereavement process, they may take up to three (3) work days for the death of an "immediate family" member (defined previously in

this handbook) or an aunt, uncle or grandparent. Employees who request additional time off must use vacation time and or personal day.

Employees should report the need for bereavement leave to their immediate supervisor as soon as feasibly possible. Proper documentation such as a newspaper clipping or a flyer or handout from the funeral may be necessary to provide to your immediate supervisor and attached to the time record for the period the leave was taken. The 3-day leave must include the day of the funeral.

Inclement Weather

There may be times that, due to severe weather conditions, it is unsafe for employees to travel to and from their work site. Hazardous travel conditions usually occur during the winter months (December, January, February, and March). Employees scheduled to work on a day management closes the Clinic due to inclement weather will be paid at their regular rate for the number of hours they were scheduled. However, employees who do not report to work due to weather conditions during times not excused by management will be required to use vacation time.

Legal Obligations

Occasionally, a legal obligation outside an employee's control will cause them to be absent from work. Typically, those absences arise as a result of the employee's summons to serve on jury duty or when subpoenaed to testify in a judicial, legislative, or administrative proceeding.

When an employee is required to attend these types of legal obligations, the Clinic will pay the employee the difference between any compensation they received for legally mandated service and regular earnings during that same time. Such compensatory payment may not exceed what the employee would have earned during a regularly schedule work week and is not to exceed forty (40) work hours. The employee is required to produce proper documentation of pay and service.

The employee must notify his or her immediate supervisor of the need for leave as soon as feasibly possible. The need for leave must be documented in writing. Examples of appropriate documentation include; jury summons, subpoena, and court or administrative body orders.

Military Leave

The Uniformed Services Employment and Reemployment Rights Act of 1994 (USERRA) governs reemployment after military service and protects against discrimination based on military service or training.

Leave will be granted, without pay, to an employee who may be required as a member of the Armed Forces of the United States to perform service. Individuals who may be required to perform such service are required to provide the Clinic with advanced notice and must return to work at the end of such service in a timely manner as outlined in USERRA.

During the period of military leave, employees may continue group health insurance through COBRA for up to twenty four (24) months as outlined in USERRA. During leave, employees will not accrue paid sick and vacation. When the employee returns, the employer must reinstate the employee's health insurance coverage with no waiting period and no exclusion of preexisting conditions except for conditions determined to be military service connected.

When an employee returns to work from Military Leave they will be reinstated to the same or comparable job and benefits they would have if they had not been on leave.

EMPLOYEE BENEFITS

Mandatory Benefits

The benefits listed below, which are mandated by federal, state or local law, are paid by the Clinic for all employees.

- A. Social Security and Medicare, also known as FICA, which is a payroll-based tax paid to the federal government to operate the national retirement and permanent disability program.
- B. State Unemployment Tax, also known as SUTA, which is a payroll-based tax paid to the Missouri government to operate the state's unemployment insurance program.
- C. Worker's Compensation which is an insurance policy that pays the medical costs for work-related injuries sustained by employees. In any situation involving work related injury the employee must immediately inform their supervisor, a Director, or the Executive Director and complete an Incident Report.

Voluntary Benefits

The benefits listed below are voluntarily offered by the Clinic to eligible employees. They are subject to change at the sole discretion of the Clinic. Any changes will be communicated to employees in writing.

A. Medical and dental insurance is available to all employees who work at least thirty-two (32) hours per week. The Clinic contributes a set dollar amount for employee health care insurance. Insurance coverage is the employees' responsibility above the Clinic contribution.

Note: The Clinic's medical services are accessible to employees only during the first 60 days of hire if they do not have insurance coverage. During that period, employees may receive medical care which is within the scope of practice of the Clinic. Employees seeking care will not receive preferential treatment in regard to appointments, providers, medications or other services. The care our Clinic provides is intended for use by those who do not have access to insurance.

- B. Term-Life insurance is available to all employees who work at least thirty-two (32) hours per week. The Clinic pays the full cost of insuring the employee. Specific rules and benefits are described in the Plan's Handbook.
- C. Accidental Death and Dismemberment is available to all employees who work at least thirty-two (32) hours per week. The Clinic pays the full cost of insuring the employee. Specific rules and benefits are described in the Plan's Handbook.
- D. Long-Term Disability insurance is available to all employees who work at least thirty-two (32) hours per week. The Clinic pays the full cost of insuring the employee. Specific rules and benefits are described in the Plan's Handbook.
- E. Retirement Plan, employees scheduled to work more than **1,000 hours** per year may contribute to this pre-tax plan. The Clinic makes employer contributions to the plan on your behalf after you have completed at least one year of service and have worked 1,000 hours during a Plan year. The Clinic will begin making such contributions on the first entry date after you have satisfied those two requirements.
- F. Cafeteria Plan, employees may elect to defer compensation on a pre-tax basis for the following:
 - 1. Medical/Dental Reimbursement
 - 2. Dependent Care Reimbursement
 - 3. Medical/Dental Premiums

G. Employee Assistance Program (EAP) is a professional counseling service available for all employees to utilize. The program is available for those experiencing problems such as marital, family and relationship difficulties, vocational stress, legal and financial difficulties, and drug and/or alcohol abuse.

HIPAA as it Relates to Benefits

The Health Insurance Portability and Accountability Act of 1996 provides limited exclusions for preexisting conditions, prohibition of discrimination based on health status, guarantee renewability and availability of health coverage to certain employers and individuals and protects many workers. It also protects enrollment and decline rights and includes provisions for enrollment or declining enrollment and special enrollment periods. For more information see Human Resources.

ERISA

As a participant of the Clinic's plan you are entitled to certain rights and protections under Employee Retirement Income Security Act (ERISA) of 1974. All plan members are entitled to:

- Examine all plan documents;
- ♦ Obtain copies of plan documents and other plan information upon written request;
- ♦ Receive a summary of the plans financial report;
- ♦ Imposes duties upon 'fiduciaries' of the plan in the interest of you, other plan members and beneficiaries;
- ♦ And protects you from separation from employment or discrimination based on obtaining welfare benefits (although you can be denied with proper written explanation of reason for denial).

See your Plan Administrator for more information.

WORK SUPERVISION AND PERFORMANCE EVALUATION

Chain of Command

The Board of Directors (the Board) is responsible for adopting the policies necessary to carry out the Clinic's mission. The Board delegates its management authority to the Executive Director who is responsible for the implementing the Clinic's mission and policies. All Clinic employees are ultimately accountable to the Executive Director, who in turn is accountable to the Board.

Most employees will have one immediate supervisor. In addition to providing a guide and support for day-to-day work, the immediate supervisor is responsible for processing administrative matters such as work schedules, vacation requests, time and attendance reports, continuing education requirements, etc. In any work related or Clinic related matters you should seek assistance from your immediate supervisor first.

Performance Evaluations

Performance evaluations are to be conducted on an annual basis determined by the employee's date of hire. An annual performance evaluation does not guarantee an employee a wage increase. However, wage increases are reviewed and increases are tied directly to the annual evaluation.

Employees may receive a written performance evaluation at the completion of any training period for a new position or a position change. Employees are not generally eligible for wage increases based on performance evaluations tied to the completion of any training period.

It is at the discretion of the supervisor whether a performance evaluation is warranted as a part of a performance improvement action. If an evaluation is warranted for this reason the employee is not eligible for a wage increase tied to the evaluation.

Each performance evaluation is to be signed and dated by the supervisor and the employee to indicate that both have seen and discussed the document. The employee's signature does not necessarily indicate that the employee agrees with the performance evaluation. Employees may include their own written comments to the performance evaluation. Employees are given a copy of the performance evaluation that is entered in their personnel file.

Due to the nature of their job, some employees may receive supervisory feedback from more than one person. In such cases, other pertinent supervisory staff will provide feedback on their respective functions only. In evaluating the employee's overall performance, the immediate supervisor may obtain written information from other appropriate supervisors.

Open Door Policy

In order to promote an effective team-oriented workplace, Clinic supervisors are to maintain an "open door" policy that encourages employees to approach them with any issue that may have an impact on the workplace, their ability to perform their job and on the Clinic's ability to fulfill its mission. Supervisors must respect certain information as confidential and on a "need to know" basis; they must not share confidential information with other staff. Supervisors should refer employees in need of assistance to the Employee Assistance Program (EAP) or appropriate professionals. In all cases, supervisors **must** immediately report to the appropriate Clinic staff any information that would jeopardize patient or client care or result in any harm to any patient, client, staff or to the Clinic itself.

Employees seeking to discuss any work-related matter with Clinic management must first inform and consult their immediate supervisor. However, there may be occasions when an employee may deem it necessary to bypass their immediate supervisor and approach other members of management directly. For example, the Section on **Prohibition of Harassment and Discrimination** specifically provides for an employee to complain to the Executive Director in the case that a supervisor is the one engaging in sexual harassment against the employee. There may be other instances in which an employee may inform other management directly of a workplace problem. For that purpose, the Clinic's Executive Director shall also maintain an "open door" policy for all employees. Employees who in good faith make a complaint to the Executive Director about the misconduct of a supervisor will be free from any form of retaliation in the workplace.

STANDARDS OF CONDUCT

The Clinic expects the conduct of all of its employees to support its Mission and the integrity of the organization, thereby enhancing its credibility and acceptance in the community. Therefore, all employees are expected to observe and maintain certain standards of conduct.

Although it is not possible to list all forms of conduct, the following guidelines are provided to assist employees in understanding what the Clinic's expectations are:

Clinic HIPAA Regulations and Confidentiality of Patient and Client Information The Clinic complies with all HIPAA regulations to protect the privacy and confidentiality of patient and client records. HIPAA regulations are viewed as the minimum confidentiality standards. Please review the Clinic policy and procedure manual for additional details. The Clinic may set forth more stringent standards that must be complied with by all employees.

Patients and clients should be asked to reveal only information relevant and necessary to authenticate and deliver high-quality care and services.

All substantive information revealed by patients and clients must be recorded in the patient and client's record. All records must be kept up on a timely basis; all substantive interactions with patients or clients must be documented in the appropriate chart or file within seventy-two (72) hours. Records may be generated and kept in paper form or by electronic device (computer). Only persons properly authorized by the Clinic's management will be permitted to have access to and make entries in those records. Records produced and/or stored in electronic devices will be accessed only through the use of pass codes assigned and traceable to authorized employees.

All written records that may lead to the identification of patients and clients must be kept in secure areas at all times, except when the records are needed by authorized personnel to record the delivery of services or to obtain information necessary for the delivery of services. Computer screens that may contain patient or client-identifying information must be attended to or password protected at all times. A limited number of key personnel, designated by the Clinic's management, have primary custody of written records and control physical access (have keys and/or pass codes) to locked areas, cabinets or electronic storage devices.

Records containing patient and client-identifying information will be kept on Clinic premises at all times; however, the Clinic's management may, for good cause, waive this requirement in writing on a case-by-case basis.

Any written records containing patient and client-identifying information **must** be **shredded** prior to being discarded. Any computers or diskettes containing patient and client-identifying information **must** be **overwritten** prior to being discarded.

Employees are prohibited from disclosing **any** patient or client information, including patient or clients' names, to **any** party outside of the Clinic. Only properly authorized personnel may disclose information, after a written consent for disclosure is signed by the patient or client and received by the appropriate Clinic employee. All such written consents for disclosure shall be kept in the patients or clients' file(s).

Employees are prohibited from discussing among themselves, on or outside of Clinic premises, patient or client information that is unnecessary and/or unimportant to the delivery of high-quality services.

The Clinic considers all information obtained in the course of the doctor-patient relationship to be not only confidential, but also legally privileged, and reserves the right to assert all legal defenses available for the protection of such relationships.

Pursuant to Missouri statute, the Clinic must report to local health directors certain communicable diseases and/or conditions for the protection of the public's health. The types of reportable communicable diseases and/or conditions, timing, form, and manner of reporting must be in strict compliance with the rules and regulations issued by the Missouri Director of Health.

Nothing in this policy prohibits the gathering and reporting of patient or client statistics for internal or external use, provided that all information that may lead to patient or client identification is previously removed. Examples of identifiable information are patients or client's name, date of birth or social security number, use of identifiable information for external reporting purposes is prohibited unless required by Missouri statute.

All employees are responsible to read and familiarize themselves with the Clinic's HIPPA and Confidentiality policy at the beginning of employment at the Clinic and a signed statement to that effect shall be kept in the employee's personnel file.

Any violation of this policy constitutes employee misconduct and as a violation of Clinic Policy is subject to immediate corrective action up to and including separation from employment. Moreover, certain federal, state and local statutes on the confidentiality of medical records carry criminal penalties for their violations. It is the Clinic's policy to prosecute the violation of confidentiality statutes.

Prohibition of Harassment and Discrimination

Consistent with the Clinic's Mission, Core Values and Equal Employment policy, all employees of the Clinic are expected to treat others with dignity and respect.

Discrimination and Harassment on the basis of race, color, sex (same or opposite sex), gender, transgender, pregnancy, religion, national origin, age, physical or mental disability, veteran status, sexual orientation or any other basis protected by federal, state or local law will not be tolerated with respect to such things as:

- Verbal harassment, including racial or sexual remarks and racially or sexually derogatory comments or slurs;
- ♦ Visual harassment, including racially or sexually derogatory words, markings, posters, cartoons, drawings, etc.;
- Physical interference with normal work or movement; or
- ♦ Unwelcome sexual touching or advances, including requests for sexual favors.

Any individual engaging in harassment, either directly or indirectly, may be subject to appropriate corrective action up to and including separation from employment.

Sexual Harassment

If directed to another individual, certain verbal and physical conduct of a sexual nature may constitute sexual harassment when: (1) submission to such conduct is made either explicitly or implicitly a term or condition of an individual's employment; (2) submission to or rejection of such conduct by an individual is used as the basis of employment decisions affecting such individual; (3) such conduct has the purpose or effect of unreasonably interfering with an individual's work performance or creating an intimidating, hostile or offensive working environment. No supervisor or other employee shall threaten or insinuate, either explicitly or implicitly, that another employee's or applicant's refusal to submit to conduct of a sexual nature will adversely affect that person's employment. Similarly, no supervisor or other employee shall promise, imply or grant preferential treatment in connection with another employee or applicant engaging in sexual conduct.

Complaint Procedure

The Clinic seeks to ensure that any complaints are addressed and resolved in an orderly and effective manner. If you believe that you are being harassed or discriminated against due to your race, color, sex (same or opposite sex), gender, transgender, pregnancy, religion, national origin, age, physical or mental disability, veteran status, sexual orientation, the incident should be immediately reported to your supervisory staff, or to Human Resources. This reporting procedure should be used to report all complaints of harassment and discrimination involving any person(s) dealt with in the workplace, including but not limited to, supervisory employees, fellow employees, vendors, volunteers, or patients/clients.

It is the responsibility of every employee to report incidents of harassment and discrimination and cooperate with any investigation. You are urged to promptly report all circumstances that may constitute harassment of yourself or another employee so the Clinic will be aware of the situation and may make an investigation and take appropriate corrective action. Your complaint will be kept as confidential as possible and you will not be penalized or retaliated against in any way for reporting such conduct, as long as your report is made in good faith. In addition, there will be no retaliation against any persons who aid, assist or give information in support of such a complaint.

Any complaint of retaliation should also be brought to the attention of the next level of supervision or Human Resources. Please do not assume that the Clinic is aware of a problem. It is your responsibility to bring complaints and concerns to our attention so that we may resolve them.

Tobacco

It is the Clinic's responsibility, as a healthcare provider, to address known hazards to our employees, patients and the public and to create a healthful, safe and comfortable environment. To help us accomplish this and in keeping with [STATE] law regarding no smoking in health Clinics, the Clinic is a tobacco free environment.

The use of tobacco products of any type is prohibited on the entire Clinic's owned and/ or leased property. This applies to employees, patients, clients, students, volunteers and visitors to our facilities. It also includes grounds, parking lots and employee vehicles parked on Clinic owned and/or leased property. Any violation to this policy will lead to immediate corrective action up to including separation from employment.

Alcohol and Drug Free Workplace

The Clinic is committed to a safe and healthy work environment. It is our belief that drug and alcohol abuse pose a serious risk, not only to the individual, but also to other employees and the patients/clients we serve. As such we are committed to an alcohol and drug free workplace. In addition, as the recipient of federal funds which require the maintenance of a drug free workplace, we wish to make it known that it is our policy to comply with legislation mandating us to provide a drug free workplace.

The Clinic strictly prohibits the manufacture, distribution, dispensation, possession or use of, or being under the influence of, any controlled substance, such as but not limited to, illegal drugs, illegal use of prescription drugs, and alcohol, on the Clinic's premises or while engaged in Clinic sponsored activities. Any employee in violation of this policy will be subject to corrective action up to and including separation from employment.

There are a few exceptions related to board and fundraising events that alcohol may be present at Clinic functions, in these instances the Clinic reserves the right to take corrective action up to and including separation from employment for any conduct that may endanger the safety of others, or damage the reputation and work of the Clinic.

Any employees whose off-duty use of alcohol or illegal or prescription drugs is the cause of work related accidents or poor work performance will be subject to corrective action up to and including separation from employment.

Employees convicted of or pleading "guilty" or "no contest" to criminal offenses related to drugs and alcohol committed on Clinic premises or while conducting Clinic business is required to notify their supervisor within five (5) working days. Failure to provide required

notice will subject the employee to immediate corrective action up to and including separation from employment.

Employees must report to work mentally and physically fit to perform their job duties. Employees on physician prescribed medication may use legally prescribed medications on the job, but only if such medication does not affect the essential functions of the job, the safety and welfare of others, or endanger the employee or others.

Testing for Drug and Alcohol Usage

In accordance with our commitment to maintaining an alcohol and drug free workplace, employees, whether suspected of violating this policy or not, may be required at the expense of the Clinic, to submit to drug/alcohol screening.

An employee who tests positive or fails to submit to a required drug test will be subject to corrective action up to and including separation from employment.

Rehabilitation Leave

An employee who feels that they have developed an addiction or dependence on alcohol or drugs is encouraged to seek assistance. Requests for assistance will be kept as confidential as possible. To obtain leave for treatment, an employee may submit in writing or request a personal appointment with their immediate supervisor or any Director.

Rehabilitation itself is the responsibility of the employee. An employee seeking medical attention for alcoholism or drug addiction may continue such benefits as are provided under the Clinic's insurance program on the same basis and with the same restrictions and limits as other leave for illnesses.

The Clinic may grant rehabilitation leave without pay for a period of not more than sixty (60) calendar days. Extensions of rehabilitation leave for not more than an additional sixty (60) calendar days may be granted at the discretion of the Executive Director.

Eligibility for Leave

The employee requesting leave must have been employed with the Clinic for at least one (1) full year of continuous employment prior to leave. The employee must also provide certification that they are enrolled in a bona fide treatment program. Further, rehabilitation leave will be granted only once per employee.

Prohibition of Firearms

No employee of the Clinic shall carry or use a firearm on Clinic premises. Any violation of firearms prohibition will result in corrective action up to and including separation from employment.

Workplace Environment

In order to optimize healthy outcomes and patient, client satisfaction, employees should maintain a respectful, courteous, friendly, cooperative and supportive nature toward patients, clients, co-workers, volunteers and visitors.

Violence in the Workplace

Consistent with and in addition to the Clinic's commitment to a healthy and safe work environment, violence in the workplace whether directed toward, but not limited to, fellow employees, patients, clients, volunteers, vendors, or any other persons on Clinic property, or attending Clinic functions, or anyone that employees may be in contact with during the course of Clinic business will not be tolerated. Any such conduct, including but not limited to, either explicit behavior such as hitting, biting, pinching, pushing, slapping, or carrying a firearm, or implicit behavior such as direct or implied threats, verbal accosting, intimidation, or other similar behavior, will lead to immediate corrective action up to and including separation from employment.

It is the responsibility of every employee to report any suspected violent, threatening, or otherwise inappropriate behavior to their immediate supervisor, the next level of supervision or Human Resources. Please follow the complaint procedure as outline in the Prohibition of Harassment and Discrimination Section of this handbook. Your complaint will be kept as confidential as possible and you will not be retaliated against in any way for reporting such conduct, assuming that your report is in good faith. It is also the responsibility of each employee to cooperate in any investigation. There will be no retaliation against any persons who aid, assist or give information in support of such complaint.

Immediate Threats of Danger

In the case of an immediate threat to the physical safety of any individual, employees are encouraged to contact law enforcement authorities immediately. In any situation when law enforcement has been contacted, employees must immediately inform their supervisor, the Director of Finance and Administration (or in the case of an absence another Director or the Executive Director), the front desk, and complete an Incident Report. In such cases

where there are threats of violence but employees are not on Clinic property, employees are encouraged to seek and follow the guidelines of that location if available or to follow Clinic guidelines if they are at a home visit.

Clinic Property

The Clinic is a publicly supported non-profit agency whose limited financial resources must be used only in the furtherance of its mission. Employees are responsible for all property, materials, or written information issued to them or in their possession or control. Employees must refrain from using the Clinic's property for personal purposes. Unauthorized possession or use of company property of any kind may lead to corrective action up to and including separation from employment.

Employees and volunteers are expected to protect and maintain confidentiality regarding the Clinic's property including cash, equipment, records, employee, patient, and client information.

Return of Property

Employees must return all Clinic property, including but not limited to, keys, pagers, or equipment immediately upon request or upon separation from employment of employment. Where permitted by applicable law, the Clinic may withhold from the employee's final paycheck the cost of any items that are not returned when required. The Clinic may also take action deemed appropriate to recover or protect its property.

The Media

Employees are prohibited from speaking with any member of the media on behalf of the Clinic except when acting with the prior approval of the Executive Director. Employees should be careful to avoid the appearance of representing the Clinic's views or positions to any member of the media through any discussion with representatives of the media.

Only the Executive Director will represent the Clinic to the media with the exception of the Director of Development who may assume the responsibility of dealing with media in the Executive Director's absence.

All inquiries or requests for information from the media about any Clinic activity, program, incident, position, etc., must be directed to the Executive Director, Director of Development or if unavailable another Development staff person.

Gifts and Rebates

Employees are prohibited from receiving commissions, gratuities, or any form of monetary reward from any outside entity or person seeking to do business with the Clinic or any Clinic patient or client. Employees may make exceptions for small items or tokens of appreciation, such as pencils, mugs, flowers, lunch, etc. from vendors who distribute such small items as a regular part of their promotions so long as accepting such items does not indicate any unauthorized commitments on behalf of the Clinic.

Patient and Client Transportation

Employees may not provide transportation for clients or patients. In the rare instance of an emergency in a work related situation, an employee must have authorization from their Department Director or the Executive Director prior to transporting a patient or client. Every effort should be made to avoid this situation. All other avenues should be exhausted first such as calling 911 for emergency or ambulance services, calling the patient and client's friend or family member, or calling a taxi cab.

Use of Telephone, Electronic Mail and Internet Systems

The Clinic has established the following policy with regard to access and disclosure of voicemail messages (voicemail), electronic mail messages (e-mail), internet services (internet), instant messaging (IM) or any message created, sent or received by all employees using the company provided telephone, e-mail or internet systems referred to as mail/internet. The Clinic provides and maintains mail/internet to assist employees in conducting company business. The mail/internet system hardware and software is Clinic property. All messages composed, sent and received on any mail/internet system provided by the Clinic also are and remains property of the Clinic. Messages are not personal, private or employee property and should not be considered such. Privacy applies where company and HIPAA confidentiality apply and then certain authorized individuals may have access to read and review any such messages or mail/internet use.

Personal Use

Telephone lines must be kept clear for business calls and emergency use. Employees are discouraged from making and receiving personal telephone calls during regular business hours and are encouraged to make all personal calls during lunch or break times.

Violations

The mail/internet system may not be used to create any offensive or disruptive messages as defined in the **Prohibition of Harassment and Discrimination** section of this handbook or in violation of any other Clinic policy or practice. This includes using mail/internet

for soliciting or promoting commercial ventures, political causes, outside organizations, and other non-job-related solicitations. Mail/internet may not be used to send, upload, receive or download copyrighted materials, trade secrets, proprietary Clinic or financial information or similar materials without prior authorization of the owner, vendor or Clinic. Employees shall not use a code, access a file, or retrieve any stored information, unless authorized to do so. Employees should not attempt to gain access to another employee's messages without the employee's permission. All computer pass codes must be provided to supervisors upon request. An employee who discovers a violation of this policy shall notify their supervisor, the next level of supervision, Human Resources or the Executive Director immediately. Any employee who violates this policy or uses mail/internet for improper purposes shall be subject to corrective action up to and including separation from employment.

Expectation of Privacy

Mail/internet is not intended to provide employees with a reasonable expectation of privacy because the Clinic reserves the right and intends to exercise the right to review, audit, intercept, access and disclose all messages created, received, or sent over the mail/internet for any purpose. The contents of mail/internet information properly obtained for legitimate business purposes may be disclosed within the organization without the permission of the employee. The confidentiality of any message should not be assumed. Even when a message is erased it is still possible to retrieve and read that message. Furthermore the use of passwords for security does not guarantee confidentiality. Notwithstanding the organizations right to retrieve and read messages, such messages should be treated as confidential by other employees and accessed only by the intended recipient. Employees are not authorized to retrieve and read any messages that are not sent to them. Any exception to this policy must receive prior approval from a Director, Human Resources or the Executive Director.

Prohibition of Political Activity

While on duty, or while present on Clinic premises, employees are prohibited from conducting any partisan political activity, whether on behalf of individual candidates or political parties, including the use of any company time, materials or systems. All advocacy activities must first be reviewed by and have prior approval from the Executive Director.

Personal Appearance Guidelines

It is the policy of the Clinic that all employees present a clean and professional image while representing the Clinic. All employees should be aware of their attire, grooming and personal hygiene.

The Clinic has a business-casual attire work week. Clothing choice should be respectful and reflect a business-office atmosphere.

Clothing items such as, bandanas, headscarves, ball caps, shorts, mini-skirts, leggings, stirrup pants, warm-up suits are not acceptable. Clothing that is tight to the body or revealing is also unacceptable. Stocking feet is prohibited at all times.

Employees who perform the majority of their work in the Clinic area or perform any functions in the laboratory must adhere to OSHA regulations and wear closed-toe shoes.

Casual Friday

Friday is considered "casual day" for employees at the Clinic. Clothing items described above as unacceptable are prohibited at all times. Denim jeans, as long as they are clean and neat, are acceptable on Casual Fridays *only*. Care should be taken to maintain a professional image to clients and other staff members every day.

All supervisors are expected to enforce the Personal Appearance guidelines. Employees wearing unacceptable attire may be sent home to change, if after being sent home any violations continue, employees are subject to corrective action up to and including separation from employment.

Outreach Activities

The nature of the outreach services the Clinic provides require our employees to assimilate and be comfortable within the environment they serve. Because of this, outreach employees clothing choices may be different with regard to these guidelines. The outreach service employee's supervisor may determine exceptions to appropriate attire.

Conduct Summarization

Since it is not possible to list all forms of misconduct, the following are some examples of infractions of rules that may result in corrective action up to and including possible immediate separation from employment:

- ♦ Theft, damage, or inappropriate removal or possession of Clinic property;
- ♦ Falsification of timekeeping, financial or any other Clinic record or form;
- A Reporting to work under the influence of alcohol or illegal drug use;
- Insubordination, abusive language, or other disrespectful conduct;
- Sexual or any other unlawful harassment;

- ♦ Excessive tardiness, absenteeism or any absences without notice;
- ♦ Violations of this handbook, policies or any standards set by the Board of Directors;
- ♦ Unsatisfactory performance or conduct;
- Any act or conduct including violence or aggression or any conduct that may endanger the safety of others, or damage the reputation and work of the Clinic; and
- ♦ The willful, deliberate or repeated violation of any Clinic rules.

The above list is not intended to be all inclusive. Employment with the Clinic is "at-will" and either party may terminate that relationship at any time, with or without advanced notice.

ETHICS POLICY

The purpose for this Ethics Policy is to support a culture of openness, trust, and integrity in all of the Clinic's management and business practices. A well-understood Ethics Policy requires the participation and support of every Clinic employee, board member and volunteer.

The Clinic is dedicated to working with our employees, volunteers, board and community partners to meet our goal of bringing quality health services to those without or limited access to care. We are committed to conducting all affairs and activities with the highest standards of ethical conduct. Our Standards of Conduct and Our Values along with professional codes of conduct provide guidance for decisions and actions during our daily work.

Code of Ethics

The Clinic employees must:

- De honest and ethical in all conduct, including ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- Comply with applicable government laws, rules and regulations. Comply with any ethical codes or bylaws that may govern professional conduct;
- Maintain the confidentiality of protected health information under HIPAA regulations. Disclosure information only when authorized by the patient and client or otherwise legally obligated to disclose;

- Deal fairly with funders, suppliers, competitors, volunteers, and employees;
- Provide patients and clients, board, constituents, funders, and collaborating partners with information that is accurate, objective, relevant, timely, and understandable;
- ♦ Promote ethical behavior as a responsible partner among peers in the work environment;
- Protect and ensure the proper use of company assets;
- ♦ Prohibit improper or fraudulent influence over the External Auditor.

Conflict of Interest

The underlying principle of "conflict of interest" is that employees, board members and volunteers should avoid any activity, investment, or interest that might reflect unfavorably on the reputation of the Clinic.

As representatives of the Clinic, employees, board members and volunteers are obligated to place the interest of the Clinic, in any transaction involving the Clinic, ahead of any personal interest or personal gain, in addition to disclosing all facts in any situation where a potential conflict of interest may arise. Board members will excuse themselves from any discussion where they may have a conflict of interest.

Employees, board members and volunteers are expected to seek clarification of and discuss any questions about potential conflict of interest with their supervisor, or another Clinic Manager or Director.

Reporting Violations

Clinic employees, volunteers, contractors, and suppliers are expected to report any practices or actions believed to be inappropriate to their supervisor, another Clinic Manager or Director.

If you have questions or concerns about compliance with the subjects described in this policy and handbook, or you are unsure about what is the "right thing" to do, we strongly encourage you to first talk with your supervisor, another Clinic Manager or a Director. If you are still unsure what to do or you unsure about reporting violations you should discuss your concerns with Human Resources or the Executive Director.

INCIDENTS, ACCIDENTS AND INJURIES

Any work-related incidents, accidents or injuries, whether they involve employees, volunteers, patients or clients, must be reported to your supervisor, the next level of supervision, Human Resources or the Executive Director immediately. Any appropriate forms, including an Incident Report form, must be completed immediately and submitted to the proper entity in a timely manner to meet the requirements of any applicable guideline, law or regulation. All employees must follow safety practices as outlined in the Clinic Policies and Procedures.

EMPLOYEE GRIEVANCE

At times, differences may arise between the Clinic's management and an employee. When this occurs employees should make a good faith effort to resolve differences with their immediate supervisor(s), or in case of a dispute between co-workers, with the assistance of their immediate supervisor(s), prior to initiating a formal grievance proceeding. However, in cases where all attempts at resolution fail, employees may file a grievance using the procedure outlined below:

Grievance Process

Any grievance must be submitted in writing to the employees Department Director within five (5) working days following occurrence of the event for which the grievance is based. The written grievance must contain information necessary for a complete review, specifying dates and detailing the situation. Within ten (10) working days of receipt of the notice, the Department Director will make a thorough investigation. The investigation may include meeting with the employee and any witnesses or people with relevant information about the grievance. The Department Director will render a decision in writing. All steps of the grievance process must be facilitated by Human Resources. As soon as a Department Director receives notice of a grievance, they should notify Human Resources immediately.

Appeal Process

If the employee is not satisfied with the Department Director's decision, they may appeal to the Executive Director within five (5) working days after receipt of the Department Director's decision. The appeal must be in writing and must specify the reasons why the employee is not satisfied with the decision. Within twenty (20) working days the Executive Director will meet with the employee, the Department Director and any witnesses that the Executive Director deems necessary to the grievance. As soon as practical after any investigation is concluded, or within fifteen (15) working days, the Executive Director will render a decision in writing.

All grievances must be signed and dated by the grieving employee. All parties involved must treat all information pertaining to a grievance in a confidential manner. If new issues are raised

that were not raised at the beginning of the grievance process, those issues may not be included and the employee may be required to repeat the earlier steps of the grievance process.

Alternative Process

In the event that a grievance involves a Director level employee the grieving employee will follow the same initial reporting process as described above only report the grievance directly to the Executive Director. In cases involving the Executive Director, Human Resources will then initiate an appropriate grievance procedure through the President of the Board of Directors. The alternative process may only be used to bypass a Director if that Director is the specific reason for the grievance.

EMPLOYEE TRAVEL

Employees are responsible for their own transportation while traveling to and from their work site. Employees that travel to and from other work site locations, responsibility for travel and all other work-related travel costs will be handled in the manner as outlined below:

Ground Transportation

When employees use a privately owned vehicle for work-related travel, the Clinic will reimburse the employee at a mileage rate not to exceed the current IRS approved mileage rate. In order to be reimbursed, employees must keep a current record of the miles traveled on a form provided by the Clinic. The mileage record will include the date, purpose of the trip, and the mileage traveled. A photocopy of the mileage record must be attached to the Expense Report form. As a general rule, employees will be reimbursed for mileage once a month.

All employees who use their vehicles for Clinic business are required to have a valid driver's license and to maintain proper automobile/vehicle insurance. Upon employment, and at the beginning of each calendar year, employees should provide the Human Resources with a copy of a valid driver's license and proof of insurance.

If an employee's driver's license expires or becomes invalid at any time; or if vehicle insurance lapses; the employee must notify their supervisor in writing immediately. A motor vehicle report may be obtained on all employees authorized to drive as a part of their work assignment or who are authorized to operate a Clinic owned vehicle. Reports may be obtained at the time of hire, periodically throughout each year or as deemed necessary by the Clinic.

Air Travel

Occasionally, employees must travel by air for work related reasons. The employee's immediate supervisor must approve air travel prior to the purchase of any airline ticket. Air travel

must be by coach or tourist accommodation; the Clinic will not reimburse the employee for first class fare. A copy of the actual airline ticket must be filed with the proper accounting documents supporting the air travel expense.

Once the employee has reached an out of town destination by air, it may be necessary to incur additional transportation expenses. The Clinic will reimburse the employee for all such reasonable expenses, which may include bus, subway, or taxi fare. In order to be reimbursed, the employee must attach receipts to the Expense Report form. Employees should keep in mind that the Clinic will reimburse them only for transportation expenses deemed necessary to perform their work duties while out of town. For example, while taxi fare from the airport to the hotel is reimbursable, taxi fare for entertainment in the evening is not. The Executive Director may disallow reimbursement of any expenses deemed extravagant, unreasonable, and/or unrelated to the work purpose of the trip.

Parking Fees

Necessary and reasonable parking fees incurred while engaged in work related activities are also a reimbursable expense. In order to be reimbursed, the employee must attach parking fee receipts to the Expense Report form.

Fines

Illegal parking fines (such as parking in a handicapped space or fire safety lane) will not be reimbursed by the Clinic. Other fines incurred by an employee while on work related travel, such as traffic violations, speeding tickets, driving while intoxicated, etc., will not be reimbursed by the Clinic and are the employees' sole responsibility.

Lodging

Necessary hotel/motel costs while out of town on business will be reimbursed by the Clinic. Hotel/motel expense reimbursement will be at actual cost. Movies, personal phone calls, (with the exception of one phone 15 minute call home per day for employees who do not have Clinic issued phone cards or Clinic issued cell phones) and other amenities charged to the hotel/motel bill are not reimbursable. A copy of the hotel/motel invoice or statement must be attached to the Expense Report form.

Meals

While out of town on business, employees will be reimbursed for breakfast, lunch, and dinner on a per diem basis. The per diem rate will be set by the Clinic.

Travel Advances

Certain types of work related travel require a substantial cash outlay, such as airline tickets, meals and transportation for several days in a "high cost" area. In such cases the employee may request from their immediate supervisor a travel advance to help defray those costs. All travel advance requests must be submitted in writing for approval by the employee's immediate supervisor and the Executive Director at least two (2) weeks prior to the departure time. All funds advanced prior to travel must be fully accounted for within two (2) working weeks of completing the trip. The Clinic will reimburse the employee for all reasonable and necessary expenses in excess of the travel advance. At the time of submission of the Expense Report and the Expense Report does not fully account for all the monies advanced to the employee, the employee must reimburse the Clinic for the amount advanced in excess of the actual expenses incurred.

CONTINUING EDUCATION

All employees must attend Clinic required in-house training sessions. Employees must document that they attended a training by signing and dating an attendance form.

Required

All professional employees who need to complete a prescribed number of Continuing Education Units (CEU'S) in order to maintain their licenses or certifications are required to complete those units in a timely manner. Documents of completion of any required units must be obtained by the employee and submitted to Human Resources for the employee's personnel file. Time spent at work related training and CEU's required to maintain licenses, certifications or other work related requirements will be paid for by the Clinic and will be paid at the employee's regular rate. However, all employees must have prior approval from their supervisor before scheduling or attending any training or CEU etc.

Voluntary

Setting and achieving continuing education objectives is an integral part of all employees' annual performance evaluation. Keeping in mind the productivity demands of one's position, employees are encouraged to work with their immediate supervisor to exceed the minimum continuing education requirements.

In respect to voluntary continuing educational activities employees may receive educational leave for the time needed in order to complete continuing education activities and the Clinic may assume some registration fees, tuition, and out-of-town travel costs associated with continuing education activities if pre-approved by the employee's Director and the Executive Director. When the cost of voluntary continuing education activities is unusually high, the employee may request the Clinic share the costs associated with the activity or event. The Clinic's participation in cost is subject to budget requirements, whether or not it is work or business related and prior approval by the Director and the Executive Director. Any cost sharing amounts are on a case-by-case basis depending on the ability of the organization to pay.

All employees are encouraged to regularly review professional journals and publications in their field of expertise. Employees are encouraged to use area libraries and "on-line" internet resources.

Employees are expected to demonstrate that knowledge acquired through continuing education activities is consistently practiced. Specifically, immediate supervisors should look for evidence that an employee's productivity has increased, that patient and client satisfaction has been enhanced, that Clinic outcomes are optimized, and that contributions to the Clinic's quality improvement efforts are consistently being made.

ISSUES NOT SPECIFICALLY COVERED IN THIS HANDBOOK

All employees are expected to comply with all Clinic rules, guidelines, policies, procedures and practices and to meet acceptable performance standards at all times. It is impossible to address all forms of behavior that may be considered unacceptable in the workplace. This handbook is intended to cover issues that may arise most often in a typical health and human service organization. Topics not specifically covered in this handbook may be addressed on a case-by-case basis by the Clinic's management or the Board of Directors.

EMPLOYEE ACKNOWLEDGEMENT FORM

The employee handbook describes important information about the [INSERT CLINIC NAME] and I understand that I should consult with my supervisor, the next level of supervision or Human Resources regarding any questions I may have.

Since the information, policies, guidelines, practice, procedures and benefits described here are subject to change, I acknowledge that the Clinic may make any revisions to the hand-book at any time. All such changes shall be communicated in writing, and revised information may supersede, modify, or eliminate policies. Only the Board of Directors has the right to adopt any revisions to the policies in this handbook.

Furthermore I acknowledge that the Clinic is an "at-will" employer. Nothing set forth in this handbook is a contract or assurance of continued compensation, employment or benefits of any kind. The Clinic retains the right to discharge any employee at any time for any lawful reason, with or without notice or the necessity of compliance with any written or unwritten policy, practice, guideline or procedure.

I have received the handbook, and I understand that it is my responsibility to read and familiarize myself with the information contained in this handbook and any revisions made to it.

Employee Signat	ure Date
Employee Name	(please print full name)
Employee Ch	necklist
Please initial	
	Employment Application Completed
	I-9 Form Completed (with appropriate documentation attached)
	Federal W-4 Form Completed
	Missouri W-4 Form Completed
	Direct Deposit Explained
	Direct Deposit Form Completed
	Mail Checks to Address Shown on Employee Information Form

	Employee Information Form Completed			
	Time Sheet Explained			
	Payroll Schedule/Pay Dates Received and Explained			
	Benefits Explained			
	Applicable Benefits Materials/Forms Received			
I understand that the above forms must be completed at the time of hire and must be legally accurate. I also understand that if any benefits forms are not completed and return				
to Human Resources prior to eligibility I may lose the opportunity to participate.				
Employee Initials/D	Pate			
Supervisor or HR I	nitials/Date			

APPENDIX C Harrassment Policy

Sexual/Personal Harassment Policy

The National Association of Free and Charitable Clinics (NAFC) is committee to an environment for its employees that is free of harassment of discrimination on the basis of gender, color, race, national origin, religion, age, sexual orientation or disability. Such conduct is defined by the Equal Employment Opportunity Commission (EEOC) as 1) Unwelcome sexual advances, request for sexual favors, or other verbal or physical acts of a sexual or sex-based nature where submission to such conduct is made either explicitly or implicitly a term or condition of an individual's employment; 2) An employment decision is based on an individual's acceptance or rejection of such conduct; 3) Such conduct interferes with an individuals work performance or creates an intimidating, hostile or offensive work environment.

Prohibited conduct includes conduct intended as humor. Sexual advances by an employee or other forms of personal harassment that unreasonably interfere with performance or create an intimidating, hostile or offensive working environment will not be tolerated. Prohibited conduct includes sexual advances, requests for sexual favors, unwelcome or offensive touching and other verbal, graphic, or physical conduct of a sexual nature.

The term personal harassment also includes, but is not limited to verbal, non-verbal or physical conduct relating to an individual's race, color, sex, religion, national origin, citizenship, age or disability.

Employees who feel they are a victim of a bona fine harassment should file a good faith report of the situation/incidents(s) to the Executive Director, or in the case of the Executive Director, to the Chairman of the Board.

The matter will be thoroughly investigated immediate action on a confidential basis, and where appropriate, disciplinary action or termination of employment will occur. Employees will not be penalized in any way for reporting such conduct concerning yourself or another person. Do not assume that the NAFC is aware of the problem. It is the employee's responsibility to bring complaints and concerns to management's attention, so that management can help resolve them.

Any employee, who is found after appropriate investigation, to have engaged in prohibited conduct of an employee will be subject to disciplinary action, including termination, as provided in the NAFC personnel policies.

APPENDIX D Executive Director Job Description

[Position Title]

[Organization Name]

I. Title

Executive Director

II. Overall Responsibility

Responsible for the operations, staffing, finances, direction and administration of [ORGANIZATION NAME]. Overall organization of ORGANIZATION, staff and ORGANIZATION functions are under the direction of the Executive Director.

III. Accountability

Accountable to and receives direction from the Board of Directors.

IV. Responsibility

A. Administrative:

- Participate in recruitment, interview, selection, disciplining and evaluation process for directly supervised staff and other key positions. Hiring, evaluating and disciplining ORGANIZATION staff is the responsibility of the Executive Director. Recruit volunteers and provide for their orientation, training, and evaluation.
- 2. Convene and lead the Management Team to ensure delivery of quality services and programs.
- 3. Maintain administrative reports and statistical information on all aspects of the ORGANIZATION.
- 4. Prepare and maintain budgets, all necessary financial reporting, assure that ORGANIZATION utilizes general acceptable accounting practices (GAAP).
- 5. Writes grants and secures funds to assure that ORGANIZATION has a sound financial base and can grow as necessary.
- 6. Functions and administers ORGANIZATION under Personnel Policies, fiscal policies and other policies and procedures adopted by the Board of Directors.
- 7. Plan and be responsible for compliance with all legal requirements of the ORGANIZATION functions and programs and the physical facility.

- 8. Undertake routine assessment of ORGANIZATION functions and make necessary changes in line with the expansion of service and efficient ORGANIZATION operations.
- 9. Organize, plan, supervise, coordinate and assign work to ORGANIZATION staff.
- 10. Recommend total personnel wage to the board as part of the annual budget presentation to the Board.
- 11. Oversee all operational and administrative functions of the ORGANIZATION.
- 12. Other duties necessary to assure that the ORGANIZATION is operating in an efficient manner.

B. Other Regular Duties:

- 1. Purchase equipment, supplies, furniture, medications and other supplies needed for the ORGANIZATION operations and when appropriate under adopted policies and procedures.
- 2. Maintain the ORGANIZATION physical site and make adjustments in layout as appropriate for staff and patient growth.
- 3. Manage the ORGANIZATION in line with the established goals, aims and objectives expressed by the Board.
- 4. Responsible for the application, implementation and interpretation of established Board policies in the operation of the ORGANIZATION and oversight of all staff. Acts as the liaison between the Board of Directors and the ORGANIZATION staff.
- 5. Attends all meetings of the Board of Directors, committee meetings, and provides direction and input into decisions affecting the ORGANIZATION and its staff.
- 6. Support the Board of Directors
 - a. ensure integrity and strength of Board leadership and address issues around clarity of role, governance, bylaws/policies and corporate structure.
 - b. assist with the cultivation and recruitment of new Board members.
 - c. prepare Executive reports to the Board of Directors and the Executive Committee.
 - d. provide staff support and attend various Committee meetings.
- 7. Between Board meetings, the Executive Director is to provide, as appropriate, general information, policy changes, and developments to the President or Vice-president of the Board.
- 8. Strategize the organization's short range and long range program goals particularly in organizing and planning:
 - a. work with the Management team to ensure quality programs and services are provided.

- b. work with the Development Director to identify overall resource development goals and fund-raising plan.
- c. establish, cultivate and maintain relations with donors, foundations, and other resources to support organizational programs and activities.
- d. maintain accountability for current year operating budget.
- 9. Other duties as assigned by the Board of Directors.

C. Special Assignments:

- Must be cognizant of and maintain regular contact with all available funding resources and prepare applications, submit applications and report secured funding to the Board. Executive Director is authorized to undertake necessary execution of grant documents to secure funding.
- 2. Maintain a high level of public acceptance, interaction with medical community and community at large necessary to maintain the future success of the ORGANIZATION.
- 3. Serve as the organization's principal leader, representative and spokesperson to the greater community.
- 4. Must respect full confidentiality of patient records, treat patients with respect and care and lead staff in that regard.

V. Skills and Knowledge Required

- A. Thorough knowledge of administration, grant writing, management and general understanding of the health care delivery system.
- B. Skills in interpersonal, community and group relations.
- C. Ability to exercise sound leadership and judgment.
- D. Public relations knowledge and expertise to maintain good public image of the ORGANIZATION.

VI. Education and experience:

Masters degree in administration, management or related field. Experience as grant writer, Executive Director or manager of health care center or similar setting/undertaking. Knowledge of financial systems, policy and procedure development and strong financial background in administration and management.

VII. Salary

Commensurate with education and experience.

APPENDIX E Nurse Job Description

[Position Title & Clinic Name]

I. Title

Nurse

II. Overall Responsibility

Nurse for Clinic, including patient education. Referral of patients for appropriate follow up care. When appropriate, can function under established medical protocols.

III. Accountability

Accountable to and receives direction from Clinic Coordinator.

IV. Responsibilities

- A. Sustaining and supporting patients during diagnosis and treatment.
- B. Obtaining health history and assessing health/illness status.
- C. Maintaining quality assurance of assigned patients.
- D. Providing patient education in the areas of health promotion and preventive medicine.
- E. Referral of patients as necessary to other health providers and/or social service agencies.
- F. Appropriate follow up of patients with chronic and acute health problems.
- G. Commensurate with education and training and when appropriate, can function under established medical protocols for minor illness and treatment of same.
- H. Other duties emanating from the Executive Director, Clinic Coordinator or Medical Policy Committee of the Board of Directors.

V. Skills and Knowledge Required

- A. Thorough knowledge of the expanding role of Nursing.
- B. General knowledge of quality assurance practices and procedures.
- C. Skills in interpersonal, community and group relations.
- D. Ability to exercise sound leadership and judgment.

VI. Education and Experience

Degree in nursing and significant experience functioning as a nurse.

VII. Salary

Commensurate with experience and education.

APPENDIX F Model COBRA Continuation Coverage General Notice

Instructions

The Department of Labor has developed a model Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) continuation coverage general notice that plans may use to provide the general notice. To use this model general notice properly, the Plan Administrator must fill in the blanks with the appropriate plan information. The Department considers use of the model general notice, to be good faith compliance with the general notice content requirements of COBRA. The use of the model notices isn't required. The model notices are provided to help facilitate compliance with the applicable notice requirements.

NOTE: Plans do *not* need to include this instruction page with the model general notice.

Paperwork Reduction Act Statement

According to the Paperwork Reduction Act of 1995 (Pub. L. 104-13) (PRA), no persons are required to respond to a collection of information unless such collection displays a valid Office of Management and Budget (OMB) control number. The Department notes that a Federal agency cannot conduct or sponsor a collection of information unless it is approved by OMB under the PRA, and displays a currently valid OMB control number, and the public is not required to respond to a collection of information unless it displays a currently valid OMB control number. See 44 U.S.C. 3507. Also, notwithstanding any other provisions of law, no person shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number. See 44 U.S.C. 3512.

The public reporting burden for this collection of information is estimated to average approximately four minutes per respondent. Interested parties are encouraged to send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the U.S. Department of Labor, Office of Policy and Research, Attention: PRA Clearance Officer, 200 Constitution Avenue, N.W., Room N-5718, Washington, DC 20210 or email ebsa.opr@dol.gov and reference the OMB Control Number 1210-0123.

OMB Control Number 1210-0123 (expires 10/31/2016)

Model General Notice of COBRA Continuation Coverage Rights

(For use by single-employer group health plans)

** Continuation Coverage Rights Under COBRA **

Introduction

You're getting this notice because you recently gained coverage under a group health plan (the Plan). This notice has important information about your right to COBRA continuation coverage, which is a temporary extension of coverage under the Plan. This notice explains COBRA continuation coverage, when it may become available to you and your family, and what you need to do to protect your right to get it. When you become eligible for COBRA, you may also become eligible for other coverage options that may cost less than COBRA continuation coverage.

The right to COBRA continuation coverage was created by a federal law, the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). COBRA continuation coverage can become available to you and other members of your family when group health coverage would otherwise end. For more information about your rights and obligations under the Plan and under federal law, you should review the Plan's Summary Plan Description or contact the Plan Administrator.

You may have other options available to you when you lose group health coverage.

For example, you may be eligible to buy an individual plan through the Health Insurance Marketplace. By enrolling in coverage through the Marketplace, you may qualify for lower costs on your monthly premiums and lower out-of-pocket costs. Additionally, you may qualify for a 30-day special enrollment period for another group health plan for which you are eligible (such as a spouse's plan), even if that plan generally doesn't accept late enrollees.

What is COBRA Continuation Coverage?

COBRA continuation coverage is a continuation of Plan coverage when it would otherwise end because of a life event. This is also called a "qualifying event." Specific qualifying events are listed later in this notice. After a qualifying event, COBRA continuation coverage must be offered to each person who is a "qualified beneficiary." You, your spouse, and your dependent children could become qualified beneficiaries if coverage under the Plan is lost because of the qualifying event. Under the Plan, qualified beneficiaries who elect COBRA continuation coverage [choose and enter appropriate information: must pay or aren't required to pay] for COBRA continuation coverage.

If you're an employee, you'll become a qualified beneficiary if you lose your coverage under the Plan because of the following qualifying events:

- ♦ Your hours of employment are reduced, or
- ♦ Your employment ends for any reason other than your gross misconduct.
- ♦ If you're the spouse of an employee, you'll become a qualified beneficiary if you lose your coverage under the Plan because of the following qualifying events:
- ♦ Your spouse dies;
- Your spouse's hours of employment are reduced;
- ♦ Your spouse's employment ends for any reason other than his or her gross misconduct;
- ♦ Your spouse becomes entitled to Medicare benefits (under Part A, Part B, or both); or
- ♦ You become divorced or legally separated from your spouse.

Your dependent children will become qualified beneficiaries if they lose coverage under the Plan because of the following qualifying events:

- The parent-employee dies;
- The parent-employee's hours of employment are reduced;
- ♦ The parent-employee's employment ends for any reason other than his or her gross misconduct;
- ♦ The parent-employee becomes entitled to Medicare benefits (Part A, Part B, or both);
- ♦ The parents become divorced or legally separated; or
- ♦ The child stops being eligible for coverage under the Plan as a "dependent child."

[If the Plan provides retiree health coverage, add the following paragraph:]

Sometimes, filing a proceeding in bankruptcy under title 11 of the United States Code can be a qualifying event. If a proceeding in bankruptcy is filed with respect to [enter name of employer sponsoring the Plan], and that bankruptcy results in the loss of coverage of any retired employee covered under the Plan, the retired employee will become a qualified beneficiary. The retired employee's spouse, surviving spouse, and dependent children will also become qualified beneficiaries if bankruptcy results in the loss of their coverage under the Plan.

When is COBRA Continuation Coverage Available?

The Plan will offer COBRA continuation coverage to qualified beneficiaries only after the Plan Administrator has been notified that a qualifying event has occurred. The employer must notify the Plan Administrator of the following qualifying events:

- ♦ The end of employment or reduction of hours of employment;
- Death of the employee;
- ♦ The employee's becoming entitled to Medicare benefits (under Part A, Part B, or both).

For all other qualifying events (divorce or legal separation of the employee and spouse or a dependent child's losing eligibility for coverage as a dependent child), you must notify the Plan Administrator within 60 days [or enter longer period permitted under the terms of the Plan] after the qualifying event occurs. You must provide this notice to: [Enter name of appropriate party]. [Add description of any additional Plan procedures for this notice, including a description of any required information or documentation.]

How is COBRA Continuation Coverage Provided?

Once the Plan Administrator receives notice that a qualifying event has occurred, COBRA continuation coverage will be offered to each of the qualified beneficiaries. Each qualified beneficiary will have an independent right to elect COBRA continuation coverage. Covered employees may elect COBRA continuation coverage on behalf of their spouses, and parents may elect COBRA continuation coverage on behalf of their children.

COBRA continuation coverage is a temporary continuation of coverage that generally lasts for 18 months due to employment termination or reduction of hours of work. Certain qualifying events, or a second qualifying event during the initial period of coverage, may permit a beneficiary to receive a maximum of 36 months of coverage.

There are also ways in which this 18-month period of COBRA continuation coverage can be extended:

1. Disability Extension of 18-month Period of COBRA Continuation Coverage

If you or anyone in your family covered under the Plan is determined by Social Security to be disabled and you notify the Plan Administrator in a timely fashion, you and your entire family may be entitled to get up to an additional 11 months of COBRA continuation coverage, for a maximum of 29 months. The disability would have to have started at some time before the 60th day of COBRA continuation coverage and must last at least until the end of the 18-month period of COBRA continuation coverage. [Add description of any additional Plan procedures for this notice, including a description of any required information or documentation, the name of the appropriate party to whom notice must be sent, and the time period for giving notice.]

2. Second Qualifying Event Extension of 18-month Period of Continuation Coverage

If your family experiences another qualifying event during the 18 months of COBRA continuation coverage, the spouse and dependent children in your family can get up to 18 additional months of COBRA continuation coverage, for a maximum of 36 months, if the Plan is properly notified about the second qualifying event. This extension may be available to the spouse and any dependent children getting COBRA continuation coverage if the employee or former employee dies; becomes entitled to Medicare benefits (under Part A, Part B, or both); gets divorced or legally separated; or if the dependent child stops being eligible under the Plan as a dependent child. This extension is only available if the second qualifying event would have caused the spouse or dependent child to lose coverage under the Plan had the first qualifying event not occurred.

Are There Other Coverage Options Besides COBRA Continuation Coverage? Yes. Instead of enrolling in COBRA continuation coverage, there may be other coverage options for you and your family through the Health Insurance Marketplace, Medicaid, or other group health plan coverage options (such as a spouse's plan) through what is called a "special enrollment period." Some of these options may cost less than COBRA continuation coverage. You can learn more about many of these options at www.healthcare.gov.

If You Have Questions

Questions concerning your Plan or your COBRA continuation coverage rights should be addressed to the contact or contacts identified below. For more information about your rights under the Employee Retirement Income Security Act (ERISA), including COBRA, the Patient Protection and Affordable Care Act, and other laws affecting group health plans, contact the nearest Regional or District Office of the U.S. Department of Labor's Employee Benefits Security Administration (EBSA) in your area or visit www.dol.gov/ebsa. (Addresses and phone numbers of Regional and District EBSA Offices are available through EBSA's website.) For more information about the Marketplace, visit www.HealthCare.gov.

Keep Your Plan Informed of Address Changes

To protect your family's rights, let the Plan Administrator know about any changes in the addresses of family members. You should also keep a copy, for your records, of any notices you send to the Plan Administrator.

Plan Contact Information

[Enter name of the Plan and name (or position), address and phone number of party or parties from whom information about the Plan and COBRA continuation coverage can be obtained on request.]

APPENDIX G Collaborative Practice Agreement

Collaborative Practice Agreement refers to the formal written statement addressing the parameters of the collaborative practice that are mutually agreed upon by the advanced practice registered nurse and one or more licensed physicians or dentists.

Collaborating Professionals refer to	
(provide Collaborating Physicians' names) and	_
· · · · · · · · · · · · · · · · · · ·	_
(provide APRN's name and licensed APRN specialty, i.e. FNP, ANP)—respectively "Physician" and "APRN"—have entered into collaborative practices (list all Physicians below):	_
	_

Clinic Practice Guidelines refers to written documents, jointly agreed upon by the collaborating professionals that describe a specific plan, arrangement, or sequence of orders, steps, or procedures to be followed or carried out in providing patient care in various Clinic situations. These may include textbooks, electronic communications, Internet references, and resources.

Responsibilities of the APRN are to see patients in a timely manner, follow practice guidelines and consult collaborating physician as needed.

Responsibilities of the Collaborating Physician are to be available for collaboration at all times either in person or electronically.

1. Methods of Patient Care—The above APRN is authorized to provide professional services within the scope of a _______ (provide APRN licensed specialty) within collaborative practice guidelines agreed upon by the collaborative parties.

The parameters of this practice include initial or follow-up assessment, history taking, physical examination of patients, and utilization of differential diagnosis, appropriate interventions, consultation and referral as indicated. Emergency treatment and stabilization are also authorized.

The parameters of this practice also include (please mark each box that is applicable):

1.	Pharmaceutical diagnostic testing
2.	Legend drugs □
3.	Controlled substances, see Addendum A, Parts 1 & 2 If APRN is requesting any controlled substances, Addendum A, Part 1 must be completed, and Addendum A, Part 2 must be signed by the APRN and all physicians.
4.	Therapeutic regimens
5.	Medical devices and appliances
6.	Receiving and distributing a therapeutic regimen of prepackaged drugs prepared and labeled by a licensed pharmacist $\ \Box$
7.	Receiving and distributing free samples supplied by a drug manufacturer $\ \Box$
8.	Receiving and distributing gratuitous drugs in controlled setting $\ \square$
	Practice Guidelines agreed upon within this collaborative arrangement are to provide guidelines for safe and effective care and will:
\Diamond	Be mutually agreed upon by the decision of the collaborating professionals.
\Diamond	Be specific to a variety of Clinic situations, and to the practice setting.
♦	Describe a general plan, arrangement, or sequence of orders, steps, or procedures to be followed in providing patient care in various Clinic situations, including medications and referral procedures.

- ♦ Be adjusted on an on-going basis to fulfill individual patient's needs/situations and to accommodate ongoing research and changing standards.
- Be maintained on site and readily available in the Clinic to the collaborating professionals.
- ♦ Be reviewed and signed yearly, or more frequently, as appropriate by both parties.

Clinic Practice Guidelines—To be utilized from among the following (list below all Clinic practice guidelines, or type and attach to CPA):

- 2. Documentation—Documentation of active medical records, such as the SOAP format will be utilized. Medical documentation will include subjective data, objective data, assessment, and recommendations for treatment, referral, and/or follow-up. Documentation will indicate cases discussed in the Clinic setting. Documentation must delineate evidence of collaboration when applicable. There is a mutual obligation and responsibility of the APRN and collaborating physician to insure acts of prescriptive authority are properly documented.
- 3. Diagnostic/Lab Requests—Diagnostic tests and/or laboratory tests, within the scope of a _______ (provide APRN licensed specialty in space), will be ordered by the APRN according to mutually agreed upon office evaluation and management practice guidelines. If results are abnormal, the APRN will follow practice guidelines utilizing appropriate consultation, treatment, and/or referral as indicated.
- 4. Medications/Prescriptions—The distribution or administration of medications by the APRN within the collaborative practice agreement shall comply with current state and federal law. The APRN will initiate pharmacological intervention not addressed by current practice guidelines only after appropriate consultation with the collaborating physician or directly.
- 5. Radiology Requests—Ordering of all radiological exams will be guided by practice guidelines. Radiological testing not addressed by current practice guidelines will be initiated only after appropriate consultation with the collaborating physician or by the physician directly.

- **6. Specialty Consults**—Specialty consultations/referrals will be completed according to practice guidelines. If need falls outside of practice guidelines, consultation with the collaborating physician and /or physician referral is required.
- 7. Hospital Admissions and Privileges—All patients who need hospital admission will be registered under the collaborating physician. The APRN will collaborate with the physician in continuing to provide care for the patients admitted by the APRN. The APRN and the collaborating physician will maintain privileges at designated hospitals.
- 8. Availability of the Collaborating Physician—the collaborating physician will be available by telephone or direct telecommunications for consultation assistance with medical emergencies, or patient referral.
- **9.** Patient Care Coverage—The APRN will \square or will not \square (please mark applicable box) participate in "on call" activities requiring medical management of patients.
- **10. Cancellation of Collaborative Arrangement**—Collaborating parties individually retain the right to terminate the collaborative arrangement with written notification of both parties.

By signing below, the APRN and collaborating physician(s) are in agreement with the APRN's level of prescriptive authority. Make as many copies of this part as needed to list and provide original signatures of all physicians. The APRN must sign each additional page:

APRN:		
Signature	Date Signed	APRN License #DEA # (if issued)
(Type or print the APRN's APRN Specialty:	s licensed name.)	
*****	****	

Physician:			
Signature	Date Signed	Medical License #	 DEA #
	e collaborating physician		
*********	*********		
Physician:			
Signature	Date Signed	Medical License #	 DEA #
	e collaborating physician	,	
*******	********		
Physician:			
Signature	Date Signed	Medical License #	 DEA #
	e collaborating physician	•	
*********	*******		
Physician:			
Signature	Date Signed	Medical License #	 DEA #
Type or print clearly the	e collaborating physician	's name.)	

Addendum A (Part 1)

Addition of Controlled Substances to this APRN's Collaborative Practice Agreement

Addendum A must be completed in full and signed by the APRN and all collaborating physicians separately on next page if any controlled substances privileges are being requested for the APRN noted below.

If this does not apply and the Collaborating Practice Agreement between the APRN and physician(s) are for **legend drugs only** then do not fill out or submit Addendum A.

APRN Name (type or print full name as licensed):
The above noted APRN is requesting approval for the following controlled substances privileges (please mark the box(es) that apply):
 □ Schedules III-V controlled substances. □ Schedule II (non-narcotic) controlled substances for ADD treatment. □ Full Schedule II narcotics controlled substances (see below).

Please Note—Full Schedule II narcotics may not be applied for with request for Initial Prescriptive Authority and should be requested *separately* than the other controlled substance schedules. The APRN requesting full Schedule II narcotics will have to appear before the next [STATE] State Board of Nursing Credentialing Committee to request approval of this level from [STATE'S BOARD OF NURSING] Board members.

By signing **Addendum A Part 2**, the APRN and all collaborating physicians agree to the following regarding the controlled substance privileges for this APRN:

1. The APRN may prescribe the controlled substance schedules marked above on this Addendum A, Part 1.

- 2. The APRN may not prescribe controlled substances in connection with the treatment of:
 - a. Chronic or intractable pain, as defined in [APPLICABLE REGULATION],
 - b. Obesity, as defined in [APPLICABLE REGULATION], or
 - c. Oneself, a spouse, child or any other family member.
- 3. The collaborating physician(s) acknowledges the responsibility to ensure that the controlled substance authority of the APRN is utilized in a manner that is consistent with any rule or regulation imposed upon the APRN's practice.

Addendum A (Part 2)

Addition of Controlled Substances to this APRN's Collaborative Practice Agreement: Approval Signatures for Controlled Substances

By signing this page, the below APRN and collaborating physician(s) are in agreement with the APRN's level of prescriptive authority with the addition of controlled substances as outlined on Addendum A, Part 1. Make as many copies of this page as needed to list and provide original signatures of all physicians. The APRN must sign each additional page.

APRN:				
 Signature	Date Signed	APRN License #	DEA #	
(Type or print clearly th	ne APRN's licensed name.)		
APRN Specialty:				
*******	*********			
Physician:				
Signature	Date Signed	Medical License #	 DEA #	
(Type or print clearly th	e collaborating physician'	s name.)		
Department of:				
*******	*******			

Physician:			
Signature	Date Signed	Medical License #	DEA #
	ne collaborating physician		
*******	*********		
Physician:			
Signature	Date Signed	Medical License #	DEA #
Department of:	e collaborating physician	•	
Physician:			
Signature	Date Signed	Medical License #	DEA #
	he collaborating physician	·	
******	********		

APPENDIX H



Comparison of Free & Charitable Clinics to Federally Funded Clinics

Universal access to health care services is a national priority. Issues currently being examined include out-of-control health care spending, poor health, and the redesign of the health care financing system. Safety-net providers -- in the form of free and charitable clinics, community health centers (CHC) and federally qualified health centers (FQHC) -- provide much needed support to fill service delivery gaps for the uninsured and underinsured. Federal 330 grants provide funds to operate the CHC/FQHC programs.

There is no equivalent funding stream for the more than 1,200 free and charitable clinics throughout the nation. Distinct variations exist between free and charitable clinics and federally funded clinics. The table below summarizes these differences.

Critical Issues	Federally Funded Clinics	Free and Charitable Clinics
Regulatory	Defined by Section 330 of the Public	Varies by locale
Agencies	Health Service Act as a FQHC or	
	FQHC look –alike. Oversight by	
	HRSA.	
Primary Funding	Federal Government Grant and	Private sector (donations, grants, etc.)
Mechanisms	Medicare; State Government-Medicaid	
	reimbursement; Insurance payers;	
	Public & Private Gifts/Grants, Self Pay	
Population	Insured/Uninsured	Uninsured/Underserved
Served		Usually up to 200% of Federal Poverty
		Level
Composition of	Federal rules require that at least 51%	Per Bylaws developed by each free
Board of	of board members be consumers	clinic
Directors		
Prescription	Medications provided through private	Free, may include a processing fee
Assistance	drug coverage benefits or at discounted	No 340b access
	pricing using the federal 340b program	
Primary Care	Provided by Clinic <i>employees</i>	Primarily and often exclusively
		volunteers
Dental Care	Provided by Clinic <i>employees</i>	Primarily and often exclusively
		volunteers
Vision Care	Referrals based on reimbursement	Referral to volunteers
Specialty Care	Referrals based on reimbursement	Provided on site by volunteers or
		through referrals at little or no cost to
		patients.
In-Patient Care	Referrals to hospitals reimbursement or	Referrals to hospitals free or sliding
	sliding fee scale	fee scale
Fees for Service	Third Party Payers or Sliding Fee	Free or Minimal fee(s) may be charged
	Scales	only if fee(s) are waived when
		necessary for essential services. Patient
		donations may be accepted.
Lab/Radiology	Referral based on reimbursement	Referrals usually free
Economic Impact	Unknown	Minimum 3:1

National Association of Free and Charitable Clinics 1800 Diagonal Road Suite 600, Alexandria, VA 22314 Phone: 703-647-7427, FAX: **866-875-3827**

APPENDIX I Donation Flyer

DONATIONS HELP THE CLINIC PROVIDE QUALITY SERVICES & MEDICATIONS AT NO CHARGE TO PATIENTS.



PLEASE MAKE A DONATION TODAY! \$5, \$10, \$15-Every \$ Helps

Endnotes

- The Free Medical Clinic must be distinguished from government Clinics, which are established, operated, and maintained by local governments for the benefit of their low-income residents. Federally Qualified Health Centers (FQHCs) and FQHC look-alikes are not Free Medical Clinics.
- The National Association of Free & Charitable Clinics, *What is a Free or Charitable Clinic?*, http://www.nafcClinics.org/about-us/what-is-free-charitable-Clinic (last visited 7/15/14).
- 3 Internal Revenue Services, Exempt Purposes–Internal Revenue Code Section 501(c)(3), http://www.irs.gov/Charities-&-Non-Profits/Charitable-Organizations/Exempt-Purposes-Internal-Revenue-Code-Section-501(c)(3) (last updated 10/30/2013).
- The Internal Revenue Services, Exemption Requirements–501(c)(3) Organizations, http://www.irs.gov/Charities-&-Non-Profits/Charitable-Organizations/Exemption-Requirements-Section-501(c)(3)-Organizations (last updates 3/13/14).
- 5 See The National Association of Free & Charitable Clinics, What is a Free or Charitable Clinic?, supra.
- 6 See The National Association of Free & Charitable Clinics, What is a Free or Charitable Clinic?, supra.
- Nat'l Ass'n of Free & Charitable Clinics, Free and Charitable Clinics Health Care Reform Talking Points, *available at* http://nafcClinics.org/sites/default/files/Free%20anc%20Charitable%20Clinic%20 Health%20Care%20Reform%20Talking%20Points.pdf.
- 8 See The National Association of Free & Charitable Clinics, Health Care Reform Talking Points, supra.
- 9 Interview with Judith Hassis, Exec. Dir, CommunityHealth Chicago (July 29, 2014).
- Ohio Association of Free Clinics, *What is a Free Clinic?*, http://www.ohiofreeClinics.org/about-us/what-is-a-free-Clinic/.
- 11 Families USA, Federal Poverty Guidelines, http://familiesusa.org/product/federal-poverty-guidelines.
- Ohio Association of Free Clinics, *What is a Free Clinic?*, http://www.ohiofreeClinics.org/about-us/what-is-a-free-Clinic/.
- 13 Reach Out Montgomery County, About, http://www.daytonreachout.org/about.html.
- 14 North Coast Health, Who do we serve?, http://northcoasthealth.org/patient-info/.
- 15 The Breathing Association, Lung Health Clinic, http://www.breathingassociation.org/lung-health-Clinic/.
- 16 Asian American Community Services, Asian Health Initiative, http://aacsohio.org/ahi-free-Clinic.
- 17 See North Coast Health, Who do we serve?.
- 18 Columbus Free Clinic, Home, http://www.columbusfreeClinic.com/.
- 19 Grace Clinic of Delaware County, How We Can Help You, http://graceClinicweb.org/.
- 20 Oxford College Corner Clinic, Clinic Services Provided, http://www.oxfordfreeClinic.org/patient-information.html.
- 21 Ashland Christian Health Center, Clinic Info, http://www.ashlandchristianhealthcenter.org/Clinic-info.html.
- AmeriCares, Free and Charitable Clinics: Helping to Fill the Mental Health Treatment Gap Among the Poor and Uninsured, May 2014, http://www.safetynetcenter.org/sites/default/files/images/Ameri-Cares%20MH%20Survey%20Report%20052914.pdf.
- For example, the Georgia Dental Association at http://www.gadental.org/charitable-clinics.html or the Virginia Oral Health Coalition at Virginia Association of Free and Charitable Clinics.
- Lewis D. Solomon & Tricia Asaro, *Community-Based Health Care: A Legal and Policy Analysis*, 24 Fordham Urb. L.J. 235, 260 (1997) (citations omitted). See also Julie S. Darnell, *Free Clinics in the United States: A Nationwide Survey*, 170 Arch Intern Med. 946, 946-53 (2010) available at http://archinte.jamanetwork.com/ (97.7% of Clinics reported that volunteer health care professionals provided some health care services).

- Stephen L. Isaacs & Paul Jellinek, *Is There a (Volunteer) Doctor in the House? Free Clinics and Volunteer Physician Referral Networks in the United States,* Health Affairs, http://content.helathaffairs.org/content/26/3/871.full (Free Medical Clinics reported that nurses (72.6%) and nurse practitioners/physician assistants (54.9%) made up a portion of their volunteer health providers).
- 26 See The National Association of Free & Charitable Clinics, What is a Free or Charitable Clinic?, supra.
- 27 IRC §§ 509(a)(1) and 170(b)(1)(A)(vi).
- Catholic Charities Free Health Center, Our Mission, https://www.freecarepgh.com/mission.cfm (last visited 7/15/14). (Catholic Charities sponsors Catholic Charities Free Health Care Center in Pittsburg, Pennsylvania, which states as its mission being "rooted in Gospel and social teaching of the Catholic Church, is dedicated to providing excellent primary health care at no charge to those who are unable to afford adequate health insurance....") Note that faith-based Free Medical Clinics must address a unique set of issues that are beyond the scope of this guidebook.
- 29 IRS Revenue Ruling 62-113 1. See also, http://www.charitableplanning.com/document/667059.
- 30 Treas. Reg. § 1.170A-1(e).
- Additional information concerning unrelated business activity and its exceptions can be found in IRS Publication 598, Tax on Unrelated Business Income of Exempt Organizations, *available at* www.irs.gov/pub/irs-pdf/p598.pdf.
- 32 IRS Publication 1771, Charitable Contributions.
- Grantspace.org, Pros and Cons, http://www.grantspace.org/Tools/Knowledge-Base/Nonprofit-Management/Establishment/pros-and-cons (last visited July 22, 2014).
- 34 Internal Revenue Service Publication 557 (last revised Oct. 2013).
- 35 A.B.A Section of Business Law Committee on Nonprofit Corporations, *Guidebook for Directors of Nonprofit Corporations* (George W. Overton et. al. eds., 2d. ed. 2002).
- 36 See A.B.A Section of Business Law Committee on Nonprofit Corporations, Guidebook for Directors of Nonprofit Corporations, supra.
- Brent Never, *Boards as Bridges*, in You and Your Nonprofit Board: Advice and Practical Tips from the Field's Top Practitioners, Researchers, and Provocateurs 177 (Terrie Temkin ed., 2013).
- 38 See Brent Never, Boards as Bridges.
- These and additional OIG resources can be accessed at http://oig.hhs.gov/compliance/compliance-guidance/compliance-resource-material.asp (last visited July 16, 2014).
- BoardSource, What Are the Legal Responsibilities of Nonprofit Boards?, The Bridgespan Group, available at http://www.bridgespan.org/Publications-and-Tools/Nonprofit-Boards/Nonprofit-Boards-101/Legal-Responsibilities-Nonprofit-Boards.aspx (last visited July 16, 2014).
- 41 See A.B.A. Section of Business Law, Guidebook for Directors, supra.
- 42 See A.B.A. Section of Business Law, Guidebook for Directors, supra.
- 43 See Gayle Gifford, Sample Job Description for Board Chair, in You and Your Nonprofit Board: Advice and Practical Tips from the Field's Top Practitioners, Researchers, and Provocateurs 293-94 app. E (Terrie Temkin ed., 2013); BoardSource, Board Job Descriptions, The Bridgespan Group, available at http://www.bridgespan.org/getdoc/c4e64a6f-b2a3-48a0-9ac7-45ee73b2f215/Board-Job-Descriptions.aspx (last visited July 16, 2014).
- See A.B.A. Section of Business Law, Guidebook for Directors, supra. (Audit committees may be held to certain additional standards); See Translating Corporate "Responsibility" Legislation and Guidance into Good Governance, Governance Series Information Bulletin #10 (Nat'l Ass'n of CMTY. Health CTRs.) Oct. 2005, available at http://www.nachc.com/client/documents/publications-resources/gov_10_05.pdf (last visited July 16, 2014).

- Some examples of descriptions for medical director positions can be found at the following sites: Safe Harbor Free Clinic: http://www.safeharborfreeClinic.org/files/volunteer_handbook_02_16_12.pdf; Heartland Community Health Center: http://heartlandhealth.org/wp-content/uploads/2013/01/ Medical-Director-Job-Description.pdf. Norfolk Community Health Center: http://www.norfolkchcc.org/pdf/employment/MedicalDirector-ClinicPhysician.pdf and http://heartlandhealth.org/wp-content/uploads/2013/01/Medical-Director-Job-Description.pdf.
- 46 See Internal Revenue Service, Exemption Requirements-501(c)(3) Organizations, supra.
- 47 U.S. Patent and Trademark Office Database *available at* http://www.uspto.gov/trademarks/process/search/.
- Form 1023: Purpose of Conflict of Interest Policy, *available at* http://www.irs.gov/Charities-&-Non-Profits/Form-1023:-Purpose-of-Conflict-of-Interest-Policy (last visited October 3, 2014).
- 49 Instructions for IRS Form 1023 available at http://www.irs.gov/pub/irs-pdf/i1023.pdf.
- Frequently Asked Questions: Form 1023, *available* at http://www.irs.gov/Charities-&-Non-Profits/Frequently-Asked-Questions-about-Form-1023.
- Form 1023, Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code available at http://www.irs.gov/uac/Form-1023,-Application-for-Recognition-of-Exemption-Under-Section-501%28c%29%283%29-of-the-Internal-Revenue-Code.
- Form 1023-EZ, Streamlined Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code, available at http://www.irs.gov/uac/About-Form-1023EZ (last visited August 26, 2014).
- 53 See Instructions for Form 1023, supra.
- NOLO Law for All, IRS Releases New Interactive Form 123, (Jan. 1, 2014) available at http://www.nolo.com/legal-update/irs-releases-new-interactive-form-1023-application-recognition-exemption-under-section-501c3-th (last visited April 2, 2015).
- See Instructions for IRS Form 1023; Charity Required Provisions for Organizing Documents, *available at* http://www.irs.gov/Charities-&-Non-Profits/Charitable-Organizations/Charity-Required-Provisions-for-Organizing-Documents (last visited October 3, 2014).
- Form 1023: Detail Required in Narrative Description of Activities, *available at* http://www.irs.gov/Charities-&-Non-Profits/Form-1023:-Detail-Required-in-Narrative-Description-of-Activities (last visited October 3, 2014).
- Form 1023: Required Information about Compensation and Other Financial Information, *available at* http://www.irs.gov/Charities-&-Non-Profits/Form-1023:-Required-Information-about-Compensation-and-Other-Financial-Information (last visited October 3, 2014).
- Form 1023: Purpose of Questions About Benefits to Members, *available at* http://www.irs.gov/ Charities-&-Non-Profits/Form-1023:-Purpose-of-Questions-About-Benefits-to-Members (last visited October 3, 2014).
- Form 1023: Required Projections of Fundraising Efforts, *available at* http://www.irs.gov/Charities-&-Non-Profits/Form-1023:-Information-About-Closely-Connected-Organizations.
- Form 1023: Information About Closely Connected Organizations, *available at* http://www.irs.gov/Charities-&-Non-Profits/Form-1023:-Information-About-Closely-Connected-Organizations (last visited October 3, 2014).
- Form 1023: Purpose of Detailed Financial Information Requested, available at http://www.irs.gov/ Charities-&-Non-Profits/Form-1023:-Purpose-of-Detailed-Financial-Information-Requested (last visited October 3, 2014).
- Form 1023: Required Financial Information, *available at* http://www.irs.gov/Charities-&-Non-Profits/Form-1023:-Required-Financial-Information (last visited October 3, 2014).

- Form 1023: Tax Periods for Which Statement of Revenue and Expenses Is Required, *available at* http://www.irs.gov/Charities-&-Non-Profits/Form-1023:-Tax-Periods-for-Which-Statement-of-Revenue-and-Expenses-Is-Required (last visited October 3, 2014).
- 64 Henry Hansmann, *The Role of Nonprofit Enterprise*, 89 YALE L.J. 837 (1980).
- 65 See Hansmann supra.
- 66 See Hansmann, supra.
- 67 Janne Gallagher, Property Tax Exemption for Charties (Evelyn Brody ed., Urb. Inst. Press 2002).
- 68 I.R.C. § 501 (2005).
- 69 See, e.g., Rev. Rul. 69-545, 1969-2 C.B. 117.
- 70 35 ILCS 5/205.
- 71 See I.R.C. § 50, supra.
- 72 See GALLAGHER, supra.
- 73 *Volunteer Licenses in Pennsylvania*, Free Clinic Associate of Pennsylvania (2013), http://freeClinicspa.org/pennsylvaniavolunteerlicensure.html.
- 74 State Practice Environment, American Association of Nurse Practitioners, http://www.aanp.org/legislation-regulation/state-legislation-regulation/state-practice-environment/66-legislation-regulation/state-practice-environment/1380-state-practice-by-type (last visited June 20, 2014).
- 75 Wis. Admin. Code N § 8.10 (2014).
- The Advisory Board Committee, *A guide to understanding state restrictions on NP practice* (2014), *available at* http://www.advisory.com/research/medical-group-strategy-council/resources/2013/understanding-state-restrictions-on-np-practice.
- Primacy Care Coalition, Compare the Education Gaps Between Primary Care Physicians and Nurse Practitioners ("Compare the Education"), http://www.tafp.org/Media/Default/Downloads/advocacy/scope-education.pdf (last visited June 20, 2014).
- Federation of State Medical Boards of the United States, *U.S. Medical Regulatory Trends and Actions* ("U.S. Medical")(May 2014), https://www.fsmb.org/Media/Default/PDF/FSMB/Publications/us_medical_regulatory_trends_actions.pdf.
- 79 Siskind Susser, PC, Chart of Physician Licensing Requirements by State, Visa Law, http://www.visalaw.com/wp-content/uploads/2014/10/physicianchart.pdf (last visited June 20, 2014).
- 80 See Federal of State Medical Boards, supra.
- National Council of State Boards, *Nurse Practice Act, Rules and Regulations*, https://www.ncsbn.org/1455.htm (last visited June 20, 2014).
- Nursing Licensure. org, *LPNs v. RNs*, http://www.nursinglicensure.org/articles/lpn-versus-rn.html (last visited June 20, 2014).
- 83 See Nursing Licensure.org, supra; see also The 2011 Uniform Licensure Requirements ("Uniform Licensure"), National Council of State Boards of Nursing at 1 (March 2012), https://www.ncsbn.org/12_ULR table adopted.pdf.
- Lending Tree Education, *State by State Nurse Practitioner Requirements ("State by State Requirements")*, http://www.degreetree.com/resources/state-by-state-nurse-practitioner-requirements (last visited June 20, 2014).
- 85 See Lending Tree Education, supra.
- Association of Social Work Boards, *About Licensing and Regulation*, http://www.aswb.org/licensees/about-licensing-and-regulation/ (last visited June 20, 2014).

- Association of Social Work Boards. *Experience and Supervision Requirements*, https://www.datapathdesign.com/ASWB/Laws/Prod/cgi-bin/LawWebRpts2DLL.dll/1lk2v7k0orjjag1ezkq6o0wal71l/\$ (last visited June 20, 2014).
- 88 See American Dental Association, Continuing Education for Dentists and Auxillaries, http://www.ada.org/~/media/ADA/Advocacy/Files/continuing_ed.ashx (contains information regaring each state's requirements).
- 89 United States Department of Health and Human Services, Health Resources and Services Administration (HRSA), *Policy Information Notice No. 2011-02* (2011), http://bphc.hrsa.gov/policiesregulations/policies/pin1102.pdf.
- 90 See United States Department of Health and Human Services, Policy Information Notice, supra.
- 91 See United States Department of Health and Human Services, Policy Information Notice No. 2011-02, supra.
- 92 U.S. Department of Health and Human Services, Office of Inspector General, *LEIE Downloadable Databases*, http://oig.hhs.gov/exclusions/exclusions_list.asp (2015).
- 93 U.S. Department of Health and Human Services, *National Practitioner Data Bank*, http://www.npdb. hrsa.gov/.
- 94 42 U.S.C. § 11101 et seq.
- 95 See United States Department of Health and Human Services, Policy Information Notice No. 2011-02, supra.
- 96 See United States Department of Health and Human Services, Policy Information Notice No. 2011-02, supra.
- 97 See United States Department of Health and Human Services, Policy Information Notice No. 2011-02, supra.
- 98 See United States Department of Health and Human Services, Policy Information Notice No. 2011-02, supra.
- 21 CFR § 205.8(a)(b) Violations and Penalties (2013). ("State Licensing laws shall provide for the suspension or revocation of licenses upon conviction of violations of Federal, State, or local drug laws or regulations, and may provide for fines, imprisonment, or civil penalties . . . State licensing laws shall provide for suspension or revocation of licensees, where appropriate, for violations of its provisions.").
- 100 21 CFR § 205.2 Terms Defined (2013) ("The purpose of this part is to implement the Prescription Drug Marketing Act by Providing minimum standards, terms, and conditions for the licensing by State licensing authorities of persons who engage in wholesale distributions in interstate commerce of prescription drugs.")
- 101 See 21 CFR 1301.13, available at http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_13.htm (Drug Enforcement Administration requires registration of manufacturers, distributors and dispensers of controlled substances. Some states have additional requirements. For example in Michigan, the Department of Licensing and Regulatory Affairs requires both the person distributing or prescribing controlled substances, as well as the business location from which the controlled substances are distributed, to obtain licenses.)
- 102 See Office of Diversion Control, supra.
- 103 42 U.S.C. § 10004 et seq.
- 104 American Society of Radiologic Technologists, State and Federal Licensure Issues, available at http://www.asrt.org/main/standards-regulations/federal-legislative-affairs/state-and-federal-licensure-issues (last accessed July 13, 2015). (According to the American Society of Radiologic Technologists, Alabama, Alaska, the District of Columbia, Idaho, Missouri, North Carolina, and South Dakota have no licensure or certification requirements.)
- See e.g. New York State Department of Health. *Radiation Equipment Registration: Frequently Asked Questions*, https://www.health.ny.gov/environmental/radiological/faqs/radequip.htm (last accessed July 13, 2014) (In New York, X-Ray machines must be registered with the New York Department of Health, Bureau of Environmental Radiation Protection.).

- 106 See generally Danny R. Veilleux, Annotation, Construction and Application of "Good Samaritan" Statutes, 68 A.L.R. 4th 294 (2014); Sharona Hoffman, Responders' Responsibility: Liability and Immunity in Public Health Emergencies, 96 Geo. L. J. 1913 (2008).
- 107 Eric A. Brandt, Good Samaritan Laws-The Legal Placebo: A Current Analysis, 17 Akron L. Rev. 303 (1983) available at http://www.uakron.edu/dotAsset/0b9e2436-8364-488b-98d7-0f3db9e11a0e.pdf.
- See Brandt, *supra*; see *e.g.*, Ala. code § 6-5-332 (listing doctors, nurses, policemen, firemen, and other designated professionals who may seek protection under the statute).
- See Brandt, *supra*; see *e.g.*, Cal. Bus. & Prof. Code § 1627.5 (providing protection at the scene of an emergency or during a declared state of emergency).
- See Brandt, *supra*; see, e.g., Ark. Code Ann. § 17-95-101 (acting as a "reasonable and prudent person would have acted under the circumstances."); Ariz. Rev. Stat. § 32-1471 (voiding immunity if "such person [rendering emergency assistance] . . . is guilty of gross negligence); and Conn. Gen. Stat. § 52-557b (gross, willful or wanton negligence voids the immunity).
- 111 See Brandt, supra; see e.g., Ark. Code Ann. § 17-95-101 (requires emergency care or assistance to be rendered without compensation).
- See Dep't of Health & Human Servs., Health Res. and Servs. Admin., *Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP)--Legal and Regulatory Issues,* app. D at 74-78 (Draft Report, May 2006) *available at* http://www.publichealthlaw.net/Research/PDF/ESAR%20 VHP%20Report.pdf.
- 113 See, e.g., N.C. Gen. Stat. § 90-21.14.
- 114 Society for Human Resource Management, *Good Samaritan Laws*, (Jan. 2014) http://www.shrm.org/legalissues/stateandlocalresources/stateandlocalstatutesandregulations/documents/goodsamaritanlaws.pdf (provides a detailed 50 state survey of good Samaritan laws).
- 115 See Society for Human Resource Management, supra.
- See, e.g., D.C. Code Ann. § 7-401 (scene of an accident or emergency, outside a hospital); Fla. Stat. § 768.13; Ky. Rev. Stat. § 411.148; and Wis. Stat. § 895.48.
- 117 See, e.g., 745 III. Comp. Stat. 49/30; N.C. Gen. Stat. § 90-21.16; N.D. Cent. Code § 32-03.1-02.2; Ohio Rev. Code § 2305.23; and Wash. Rev. Code § 4.24.300(2).
- 118 See, e.g., Md. Code Ann. Cts. & Jud. Proc. § 5-606.
- 119 745 III. Comp. Stat. 49/30(b).
- 120 Idaho Code § 5-330.
- Johnson v. Stafford, 31 Va. Cir. 397 (1993) (finding a genuine issue as to a material fact whether gross negligence was present in a Good Samaritan case) (quoting Ferguson v. Ferguson, 212 Va. 86, 92, 181 S.E.2d 648, 653 (1971)).
- 122 See Society for Human Resource Management, supra.
- 123 See Society for Human Resource Management, supra.
- 124 See, e.g., Md. Code Ann. Cts. & Jud. Proc. Code Ann. § 5-606; Ohio Rev. Code Ann. § 2305.23; and Vt. Stat. Ann. tit. 12, § 519.
- 125 745 III. Comp. Stat. 49/30.
- 126 745 III. Comp. Stat. 49/30(e).
- 127 Ohio Rev. Code Ann. § 2305.234(C) (emphasis added).
- 128 Ohio Rev. Code Ann. § 2305.234(A)(7).
- 129 Ohio Rev. Code § 2305.234(F)(1).

- 130 28 U.S.C. Part VI, ch. 171 (1946), as amended.
- 131 H.R. Rep. No. 823, Part 2, p. 5, 102nd Cong. 2nd Sess.
- U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), Health Center Program, Requirements for Medical Malpractice Coverage for Free Clinic Board Members, Officers, Employees and Individual Contractors under the Affordable Care Act Amendment to 42 U.S.C. 233(o), http://bphc.hrsa.gov/ftca/freeClinics/pal201008.html.
- 133 See generally U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), Health Center Program FTCA, http://bphc.hrsa.gov/ftca/healthcenters/index. html; U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), Federal Tort Claims Act Health Center Policy Manual (Jul. 21, 2014 ed.) available at http://bphc. hrsa.gov/policiesregulations/policies/ftcahcpolicymanualpdf.pdf (provides detailed information regarding the applicable circumstances of the Health Center FTCA Medical Malpractice Program).
- 134 See HRSA Health Center Program, Requirement for Medical Malpractice Coverage, supra.
- 135 See United States Department of Health and Human Services, Policy Information Notice, supra.
- 136 See Solomon & Asaro, Community-based Health Care, supra.
- 137 42 U.S.C. §233(o) (emphasis added).
- 138 See United States Department of Health and Human Services, Policy Information Notice, supra.
- 139 See United States Department of Health and Human Services, Policy Information Notice, supra.
- 140 42 U.S.C. § 233(o).
- 141 42 U.S.C. §§ 14501-14505.
- 142 42 U.S.C. §§ 14501-14505.
- 143 Andrew F. Popper, *A One-term tort Reform Tale: Victimizing the Vulnerable*, 35 Harv. J. on Legis. 123, 132-133.
- Nonprofit Risk Management Center, State Liability Laws for Charitable Organizations and Volunteers, (2009) available at http://www.nonprofitrisk.org/downloads/state-liability.pdf.
- Paul A. Hattis, Overcoming Barriers to Physician Volunteerism: Summary of State Laws Providing Reduced Malpractice Liability Exposure for Clinician Volunteers, 2004 U. of Ill. L. R. 167 (2004).
- Janet Fairchild, Annotation, *Tort Immunity of Nongovernmental Charities–Modern Status*, 25 A.L.R. 4th 517 (2014).
- 147 Md. Code Ann. Cts. & Jud. Proc. § 5-606.
- 148 Mass. Gen. Laws ch. 231, § 85K; S.C. Code Ann. § 33-56-180; Texas Charitable Immunity and Liability Act, Chapter 84, Texas Civil Practice and Remedies Code.
- 149 Ohio Rev. Stat. § 2305(A)&(D).
- 150 See, Interview with Judith Hassis, supra.
- International Risk Management Institute, *Glossary of Insurance & Risk Management Terms, available at* http://www.irmi.com/online/insurance-glossary/terms/v/valuation.aspx (last visited Jul. 11, 2014).
- 152 Glen Weissenberger & Barbara B. McFarland, The Law of Premise Liability, §7.01(4th ed. 2011).
- All Law.com, Who Will Pay For Your Medical Bills After an Accident?, http://www.alllaw.com/articles/nolo/personal-injury/pay-medical-bills-after-accident.html (last visited Jul. 12, 2014).
- 154 See International Risk Management Institute, supra.
- 155 Internal Revenue Service, Governance and Related Topics 501(c)(3) Organizations, available at http://www.irs.gov/pub/irs-tege/governance_practices.pdf, (last visited Jul. 12, 2014).

- 156 9A Lee R. Russ & Thomas F. Segalla, Couch on Insurance § 131:30 (3d ed. 1995).
- 157 Charitable Trust Law Developments for Tax Exempt Organizations, AHLA-PAPERS P10280217.
- 158 Maniloff, Randy J, and Jeffrey W Stempel, *General Liability Insurance Coverage : Key Issues In Every State* 531 (2nd ed. 2012).
- Marly McMillan, Jim Arend, *Before You Sign That Office Lease*, Family Practice Management, November-December 2010,17(6):17-20.
- Healthcare Facilities Solutions, Test Fit Essential Prior to Signing Medical Office Lease http://www.healthcarefs.com/news/detail.php?id=17.
- 161 See Healthcare Facilities Solutions, supra.
- 162 Section 1128B(b) of the Social Security Act (42 U.S.C. § 1320a-7b(b)).
- Andrew Dick, *Medical Office Leases: Understanding the Regulatory Requirements Behind the Lease*Terms, American Bar Association, Section of Real Property, April 30-May 1, 2009, at 6.
- 164 See Andrew Dick, supra.
- World Health Organization, *Fact sheet No.* 253, (Nov. 2007) http://www.who.int/mediacentre/fact sheets/fs253/en/.
- 166 U.S. Food and Drug Administration, *Compressed Medical Gases Guideline*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124716.htm.
- 167 21 U.S.C. § 802(6).
- 168 U.S. Dep't of Justice, Office of Civil Rights, *Americans with Disability Act: Access to Medical Care for Individuals with Mobility Disabilities*, (July 2010) http://www.ada.gov/medcare_mobility_ta/medcare_ta.htm
- 169 42 U.S.C. § 12102.
- 170 42 U.S.C. §§ 1218-1282.
- Institute of Medicine Committee on Disability in American, *The Future of Disability in America*, Washington, D.C. National Academies Press (2007) *available at* http://www.ncbi.nlm.nih.gov/books/NBK11429/ (For further discussion of the theory that an "undue burden" defense is difficult to prove in the health care setting).
- 172 42 U.S.C. § 12182(a); 29 U.S.C. § 794(a); 28 C.F.R. 36.303(a).
- 173 36 C.F.R. § 401 et seq.
- 174 See US Dep't of Justice Office of Civil Rights, supra.
- 175 28 C.F.R. 36.303(c)(1)(ii).
- 176 U.S. v. Inova Health System, *Consent Decree*, (2011) *available at* http://www.ada.gov/inova.htm (last visited August 29, 2014).
- 177 U.S. Dep't of Justice, Civil Rights Division Disability Rights Section,, *ADA Requirements: Effective Communication* (Jan. 2014) *available at* http://www.ada.gov/effective-comm.htm.
- 178 See, Interview with Judith Hassis, supra.
- 179 See, Interview with Judith Hassis, supra.
- 180 See, Interview with Judith Hassis, supra.
- 181 45 C.F.R. Part 160.
- 182 29 C.F.R. § 1910.1030.
- 183 See, Interview with Judith Hassis, supra.
- Alden Landry. *Non-Financial Barriers to Care*, Policy Prescriptions (2012) *available at* http://www.policy prescriptions.org/journal-club-non-financial-barriers-to-care/.

- 185 See, Interview with Judith Hassis, supra.
- 186 29 U.S.C. Chapter 8
- 187 U.S. Dep't of Labor Office of the Assistant Secretary for Policy, *elaws: Fair Labor Standards Act Advisor, available at* http://www.dol.gov/elaws/esa/flsa/screen75.asp.
- 188 42 U.S.C §2000d.
- 189 Executive Order 13166.
- 190 Kelly Everly Ansboury, *Risk Management and Background Checks: When it comes to your health care organization, you can't take chances*, HealthLeaders Media, (Sept. 15, 2008), http://healthleadersmedia.com/content.cfm?topic=HR&content_id=218897.
- 191 Shelly K. Schwartz, *When Patients Lie to You*, Rosewell Park Cancer Institute (2010) *available at* https://www.roswellpark.org/partners-practice/white-papers/when-patients-lie-you.
- 192 See, Interview with Judith Hassis, supra.
- 193 Am. Med. Ass'n, *Opinion 8.115–Termination of the Physician-Patient Relationship* (1996), *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8115.page.
- 194 See Tierney v Univ. of Mich. Regents, 669 N.W.2d 575 (2003).
- Louisiana State Med.Soc'y, *Healthcare Resources for the Practitioner* (2014) http://www.lsbme.la.gov/content/healthcare-resources-practitioner (noting "The legal theory of abandonment of a patient by a physician is not very well developed or defined in Louisiana, so we must look to the common law theory of abandonment and medical ethics for guidance on this issue.").
- 196 If a patient is a threat to staff, volunteers or other patients, it would be prudent to shorten or eliminate this time period all together.
- 197 Donation of Drug Samples to Charitable Institutions, 21 C.F.R. § 203.39 (2012) ("A charitable institution may receive a drug sample donated by a licensed practitioner or another charitable institution for dispensing to a patient of the charitable institution, or donate a drug sample to another charitable institution for dispensing to its patients . . . ").
- 198 Jessica Wapner, *Hurdles Facing Unused Prescription Drug Repositories*, Scientific American, (Jan. 19, 2009) *avaiable at* http://www.scientificamerican.com/article/spreading-the-health/.
- 199 See National Conference of State Legislatures, State Prescription Drug Return, Reuse and Recycling Laws (2015) available at http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx.
- 200 See 21 C.F.R. § 203.39(i) ("A charitable institution shall notify FDA within 5 working days of becoming aware of a significant loss or known theft of prescription drug samples.").
- 201 See, e.g., North Carolina Board of Pharmacy, Frequently Asked Questions About Donation and Dispensing of Prescription Drugs, Devices and Medical Supplies, http://www.ncbop.org/faqs/Pharmacist/FAQDrugSuppliesMedicalDeviceRespositoryProgr.pdf.
- 202 See 21 C.F.R. § 203.39 *supra* (requiring that a donation record be prepared at the time of collection or delivery and be kept for a period of at least three years).
- 203 See 21 C.F.R. § 203.39 *supra* ("Each recipient charitable institution shall maintain complete and accurate records of donation, receipt, inspection, inventory, dispensing, redistribution, destruction, and returns sufficient for complete accountability and auditing of drug sample stocks.").
- 204 See 21 C.F.R. § 203.39 supra.

- Partnership for Prescription Assistance, *Facts about PP*A, https://www.pparx.org/en/about_us/facts_about_ppa.
- 206 See National Conference of State Legislatures, State Pharmaceutical Assistance Programs, http://www.ncsl.org/research/health/state-pharmaceutical-assistance-programs.aspx.
- 207 Walmart, \$4 Prescriptions, http://www.walmart.com/cp/1078664?povid=cat1088607-env458327-moduleB040214-ILinkSavingsPrograms1FourDollarPrescriptions.
- Walgreens, Save Money with the Prescriptions Savings Club, http://www.walgreens.com/pharmacy/psc/psc overview page.jsp.
- 209 CVS Pharmacy, Health Savings Plan, http://www.cvs.com/content/health-savings-pass.
- 210 National Association of Free & Charitable Clinics, Discount Pharmacy Card, http://www.usarx.com/ The-National-Associationof-Free-and-Charitable-Clinics.
- Bonnie S. Cassidy, *Defining the Core Clinic Documentation Set for Coding Compliance*, (2012) available at http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1 049822.pdf.
- United States Department of Health and Human Services, *Summary of the HIPAA Privacy Rule*, http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf.
- 213 45 C.F.R. § 160.102 (2014); 45 C.F.R. § 162.
- 214 45 C.F.R. § 164.504(e) (2014).
- 215 45 C.F.R. § 160.102; § 160.103.
- 216 45 C.F.R. § 160.103 (2014).
- 217 45 C.F.R. §§ 164.522, 164.524, 164.526, and 164.528 (2014).
- 218 45 C.F.R. §§ 164.520 (2014) and 45 C.F.R. § 164.530 (2014).
- 219 45 C.F.R. §§ 164.302 164.306 (2014).
- 220 45 C.F.R. §§ 164.402–164.404 (2014).
- 221 45 C.F.R. § 164.404 (2014).
- 222 42 C.F.R. § 2.1 (2014) and 42 C.F.R. § 2.3(a) (2014).
- 223 45 C.F.R. § 164.312(a)(2)(iv) and (e)(2)(ii).
- 224 45 C.F.R. § 164.506.
- 225 45 C.F.R. § 164.506 (a).
- 226 45 C.F.R. § 164.501.
- 227 45 C.F.R. § 164.502(b); 45 C.F.R. § 164.514(d).
- 228 45 C.F.R. § 164.514(d)(3)(iii)(A).
- 229 45 C.F.R. § 164.512(f)(1)(ii)(A)-(B).
- 230 45 C.F.R. § 164.512(f)(1)(ii)(C).
- 231 45 C.F.R. § 164.512; 45 C.F.R. § 164.502.
- 232 45 C.F.R. § 164.512(j)(1)(ii)(A), 45 CFR 164.512 (j)(2)-(3).
- 233 45 C.F.R. § 164.512.
- 234 45 C.F.R. § 164.512.
- 235 45 C.F.R. § 164.512(j)(1)(i).
- 236 45 C.F.R. § 1645.512(k)(5).
- 237 45 C.F.R. § 164.512(k)(2)-(3).
- 238 45 C.F.R. § 164.512(g)(1).

- 239 45 C.F.R. § 164.508(a)(2).
- 240 42 C.F.R. § 2.63.
- 241 45 C.F.R. § 164.502; 45 C.F.R. §164.512.
- 242 45 C.F.R. § 164.522(a).
- 243 45 C.F.R. § 164.512.
- 244 73 Fed. Reg. 7914 (2008); 45 C.F.R. §164.512.
- 245 29 U.S.C. § 2613(b).
- 246 42 U.S.C. §12101 et seq.
- 247 42 U.S.C. § 12112(d)(3).
- 248 See 45 C.F.R. § 164.530; 45 C.F.R. § 164.528.
- 249 45 C.F.R. § 164.312(a)(2)(iv) and (e)(2)(ii).
- 250 See 45 C.F.R. § 164.310(d)(2)(i) and (ii).
- U.S. Department of Human Services, Office of Civil Rights, *HIPAA Privacy and Security Rules, Frequently Asked Questions About the Disposal of Protected Health Information. available at http://www.hhs.gov/ocr/privacy/hipaa/enforcement/examples/disposalfags.pdf.*
- 252 See 45 C.F.R. § 164.308(b), 164.314(a), 164.502(e), and 164.504(e).
- 253 See 45 C.F.R. § 164.530(b) and (i), as well as 164.306(a)(4) and 164.308(a)(5) with regard to electronic PHI.
- Volunteers in Health Care, Starting a Free Clinic: A Volunteers in Health Care Guide (2002), available at http://www.nafcClinics.org/sites/default/files/resources/start%20a%20free%20Clinic.pdf.
- 255 See Volunteers in Health Care supra.
- 256 See Volunteers in Health Care supra.
- See Institute for Health care Improvement (IHI), Use Regular Huddles and Staff Meetings to Plan Production and to Optimize Team Communication, Institute for Health care Improvement (last visited Aug. 12, 2014), available at http://www.ihi.org/resources/Pages/Changes/UseRegularHuddlesandStaff MeetingstoPlanProductionandtoOptimizeTeamCommunication.aspx; See Institute for Health care Improvement (IHI), Optimize the Care Team (last visited Aug. 12, 2014), available at http://www.ihi.org/resources/Pages/Changes/OptimizetheCareTeam.aspx.
- 258 See The Governance Institute, Leadership in Health care Organizations, a Guide to Joint Commission Leadership Standards 3 (2009), available at http://www.jointcommission.org/assets/1/18/wp_leadership_standards.pdf.
- 259 See IHI, Use Regular Huddles and Staff Meetings, supra.
- 260 See IHI, Use Regular Huddles and Staff Meetings, supra.
- UCSD Student-Run Free Clinic Project, *Start a Free Clinic: 25 Steps*, (2015), *available at* http://meded.ucsd.edu/freeClinic/start-free-Clinic.php.
- 262 See Peter L. Elkin & Paul N. Gorman, Continued Medical Education and Patient Safety: An Agenda for Lifelong Learning, J. AM. MED. INFORMATICS ASS'N (2002), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC419436/.
- 263 ECRI Institute, Sample Risk Management Plan for a Community Health Center Patient Safety and Risk Management Program (2010), available at http://bphc.hrsa.gov/ftca/riskmanagement/riskmgmtplan.pdf.
- U.S. Dep't of Health and Human Services, Health Resources and Service Administration (HRSA), *Risk Management and Quality Improvement*, http://bphc.hrsa.gov/ftca/riskmanagement/.
- The Henry J. Kaiser Family Foundation, *Key Facts about the Uninsured Population* (Sept. 26 2013), *available at* http://kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured-population.

- See U.S. Dep't Health and Human Services, Health Resources and Services Administratio (HRSA), Policy Information Notice 2004-24: Federal Tort Claims Act Coverage of Free Clinic Volunteer Health Care Professionals (June 18, 2009) available at http://bphc.hrsa.gov/policiesregulations/policies/pdfs/pin200424.pdf; See United States Department of Health and Human Services, Policy Information Notice No. 2011-02, supra. (To help ensure patient safety and protect patients from incompetent providers, free Clinics should not authorize providers to perform services that their qualifications do not support. When a free Clinic grants privileges to a provider, the verified qualifications used to support the free Clinic's determination that the provider has the necessary skills and expertise to perform the services for which the privileges are granted should be kept on file in a secure manner and in accordance with any applicable laws and free Clinic procedures and policies.).
- National Association of Social Workers, *Social Work and Care Coordination* 1, *available at* http://www.naswdc.org/advocacy/briefing/CareCoordinationBriefingPaper.pdf.
- 268 U.S. Dep't of Health and Human Services, Agency for Healthcare Research and Quality, *Care Coordination*, (May 2015) *available at* http://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/index.html.
- The National Coalition on Care Coordination (N3C), *Policy Brief: Implementing Care Coordination in the Patient Protection and Affordable Care Act, available at* http://www.nyam.org/social-work-leadership-institute/docs/publications/N3C-Implementing-Care-Coordination.pdf.
- 270 See National Association of Social Workers, supra.
- Office of the National Coordinator for Health Information Technology (ONC) HealthIT.gov, *Benefits of EHRs, (2014) available at* http://www.healthit.gov/providers-professionals/improved-care-coordination; Nina Brown, *Enhancing The Intersection Between Production and Promoting Quality Improvement: Focus on Quality,* (Nov. 11, 2011) at slide 41, *available at* http://www.nhchc.org/wp-content/uploads/2011/12/Quality-Improvement-vs-Productivity-Nina-Brown.pdf.
- 272 See Volunteers in Health Care supra.
- 273 See US Department of Health and Human Services, Health Resources and Services Administration (HRSA), Review of Risk Management Systems: Supplemental Information and ECRI Institute Resources Presentation, available at http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CB0QFjAA&url=http%3A%2F%2Fwww.bphc.hrsa.gov%2Fftca%2Fhealthcenters%2Friskmanagementsys.pptx&ei=OH_qU7DGMIShogSu1oHgCg&usg=AFQjCNEPcWPhRdk7QF4oXB7BYFVTLkbjUw.
- 274 21 C.F.R. § 1300.01.
- 275 See HRSA, Review of Risk Management Systems, supra.
- 276 Resnick, Barbara, *Collaboration: Foundation for a Successful Practice*, Journal of American Medical Directors Association, (Nov/Dec. 2003).
- 277 Louisiana State University Health Sciences Center New Orleans, *Generic Collaborative Practice Agreement form, available at* http://nursing.lsuhsc.edu/FacultyStaff/FacultyPractice/collaborative%20 practice%20agreement.pdf.
- 278 See, Louisiana State University, Generic Collaborative Practice Agreement Form, supra.
- 279 Ariz. Rev. Stat. Ann. § 32-2531; Cal. Code Regs. tit. 16, § 1399.540.
- Cal. Code Regs. tit. 16, § 1399.540; See California Department of Consumer Affairs, Physician Assistant Board, *Delegation of Services Agreement*, http://www.pac.ca.gov/forms_pubs/delegation_changes.shtml.

- 281 Indian Health Service, Risk Management & Medical Liability: A Manual for Indian Health Services & Tribal Health Care Professionals 23 (2d ed. 2006), available at http://www.ihs.gov/RiskManagement/index.cfm?module=dsp_rm_manual_main.
- See U.S.Dep't of Health and Human Services, Office of Inspector General (OIG), *The External Review of Hospital Quality A Call for Greater Accountability* (1999) *available at* http://oig.hhs.gov/oei/reports/oei-01-97-00050.pdf; National Network for Oral Health Access(NNOHA), *Operations Manual*, (2013) *available at* http://www.nnoha.org/resources/operations-manual/.
- 283 See NNOHA, Operations Manual, supra.
- 284 See OIG The External Review of Hospital Quality, supra.; See Volunteers in Health Care supra.
- 285 See Volunteers in Health Care supra.
- American Medical Association, *Medical Peer Review*, http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/medical-peer-review.page?.
- 287 See Anita Modak-Truran, A Fifty-State Survey of the Medical Peer Review Privilege, Butler Snow(2008) available at http://www.butlersnow.com/wp-content/uploads/pdfs/attorney_publications/case-law-a-fifty-state-survey-of-the-medical-peer-review-privilege.pdf.
- See Florida Hospital Waterman, Inc. v. Teresa M. Buster, 984 So.2d 478 (2008); Florida Peer Review After Amendment 7: Challenges and Solutions to a National Trend, Foley & Larnder LLP, Legal News: Health care (5 May, 2008), available at http://www.foley.com/florida-peer-review-after-amendment-7-challenges-and-solutions-to-a-national-trend-05-05-2008/.
- See National Heart, Lung, and Blood Institute, *About Systematic Evidence Reviews and Clinic Practice Guidelines, available at* http://www.nhlbi.nih.gov/guidelines/about.htm; US Department of Health and Human Services, *Primary Care: The Health Center Program, Use of Clinic Protocols and Clinic Practice Guidelines, available at* http://bphc.hrsa.gov/technicalassistance/resourcecenter/Clinicalservices/useof Clinicalprotocols.docx.
- 290 National Academy of Sciences, Institute of Medicine of the National Academies, *Standards for Developing Trustworthy Clinical Practice Guidelines* (Mar. 23, 2011) https://iom.nationalacademies.org/~/media/Files/Report%20Files/2011/Clinical-Practice-Guidelines-We-Can-Trust/Clinical%20Practice%20 Guidelines%202011%20Report%20Brief.pdf.
- 291 See Degelau J., Belz M., Bungum L., Flavin P.L., Harper C., Leys K., Lundquist L., Webb B. Institute for Clinic Systems Improvement. Prevention of Falls (Acute Care) (3d ed. 2012).
- Jeannie L. Haggerty et al., *Continuity of Care: A Multidisciplinary Review*, 327 BMJ 1219, 1219-1221 (2003), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC274066/.
- Vidya Sufhakar-Krishnan and Mary Rudolf, *How important is continuity of care?*, 92 Arch. Dis. Child. 381, 381 (2007), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2083711/.
- 294 Telephone Interview with Teresa Brittain, Exec. Dir., Free Med. Clinic of Oak Ridge (July 18, 2014).
- 295 Erik Olson, No Room at the Inn: A Snapshot of an American Emergency room, 46 Stan. L. Rev. 449 (1994).
- 296 Robin W. Weinick, Rachel M. Burns & Ateev Mehrotra, *Many Emergency Department Visits Could Be Managed At Urgent Care Centers and Retail Clinics*, 29 Health Affairs 1630, 1630-1636 (2010), http://content.healthaffairs.org/content/29/9/1630.full; see Robert W. Derlet et al., *Refusing care to patients who present to an emergency department*, 19 Annals of Emergency Med. 262–267 (1989), http://www.annemergmed.com/article/S0196-0644(05)82041-4/abstract.
- 297 Marisa Grimes, *Neilsen: Global Consumers' Trust in 'Earned' Advertising Grows in Importance*, Nielsen (2012) http://www.nielsen.com/us/en/press-room/2012/nielsen-global-consumers-trust-in-earned-advertising-grows.html.
- 298 See Telephone Interview with Teresa Brittain, supra.

- 299 U.S. Dep't of Health and Human Services Health Resources and Services Administration (HRSA)
 Office of Rural Health Policy, *A Manual on Effective Collaboration Between Critical Access Hospitals*and Federally Qualified Health Centers (April, 2010) available at http://www.hrsa.gov/ruralhealth/pdf/
 ghcmanual042010.pdf.
- 300 See Office of Rural Health Policy, A Manual on Effective Collaboration, supra.
- 301 Kyriacou et al., *Brief Report: Factors Affecting Outpatient Follow-Up Compliance of Emergency Department Patients*, 20 J Gen. Intern. Med. 938, 938 (2005), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1490224/.
- 302 Junod Perron et al., *Reduction of Missed Appointments at an Urban Primary Care Clinic: A Randomized Controlled Study,* 11 BMC Family Practice 79 (2010), http://www.biomedcentral.com/1471-2296/11/79.
- 303 Health Care Ass'n of N.Y *A Plan for Expanding Sustainable Community Health Centers in New York.*, (April 2013), http://nyshealthfoundation.org/uploads/resources/plan-for-expanding-sustainable-community-health-centers-ny-april-2013.pdf.
- 304 William M. Macharia, MMED et al., *An Overview of Interventions to Improve Compliance with Appointment Keeping for Medical Services,* 267 JAMA 1813, 14813-1817 (1992), http://www.ncbi.nlm.nih.gov/pubmed/1532036.
- Jacquelyn D. Phillips, Evaluating Patient Compliance: Effect of Appointment Reminder Systems on Attendance, Wright State University, (July 8, 2008), http://corescholar.libraries.wright.edu/mph/61/.
- 306 See e.g. Talk Soft, http://www.talksoftonline.com/automated-appointment-reminder-systems.shtml (an option for an automated reminder service).
- 307 Telephone Interview with Patsy Whitney, Exec. Dir., St. Luke's Free Med. Clinic (July 18, 2014).
- 308 Katherine D. Rose, Joseph S. Ross & Leora I. Horwitz, *Advanced Access Scheduling Outcomes: A Systematic Review,* 171 JAMA 1150, 1150-1159 (2011), http://archinte.jamanetwork.com/article.aspx?a rticleid=1105829.
- 309 Erik Olson, *No Room at the Inn: A Snapshot of an American Emergency room,* 46 Stan. L. Rev. 449, 492 (1994).
- David Margolius, *Using Google Docs To Facilitate Patient Flow In A Community Health Center*, Primary Care Progress (Oct. 22, 2010, 1:00 AM), http://primarycareprogress.org/blogs/16/30.; Michael K. Tran & Uyen Tran, *Managing Patient Flow in a Busy Practice*, Ophthamology Management (Apr. 4, 2011), http://www.ophthalmologymanagement.com/articleviewer.aspx?articleID=105494.
- 311 See Margolius, Using Google Docs, supra.
- 312 Some popular Patient Management Systems providers are: AllScripts (http://www.allscripts.com/en/solutions/acute-solutions/patient-flow.html), Teletracking (http://www.teletracking.com/solutions/operations.html), and ProModel (http://www.promodel.com/solutions/hospital-patient-flow.asp?gclid=CJ6C9JTNhr8CFTEV7AodkBYA0A).
- 313 Stephen Isaacs & Paul Jellinek, *Is There A (Volunteer) Doctor In The House? Free Clinics and Volunteer Physician Referral Networks in The United States*, 26 Health Affairs 871, 872 (2007), *available at* http://content.healthaffairs.org/content/26/3/871.long.
- 314 See 42 U.S.C. § 1320a-7b.
- 315 See 42 C.F.R. § 1001.952.
- 316 See Office of Public Affairs, Office of Inspector General Department of Health & Human Services, Fact Sheet November 1999, Federal Anti-Kickback Laws and Regulatory Safe Harbors (1999) available at http://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm.

- 317 See 42 U.S.C. 1320a-7d(b)) and 42 C.F.R. § 1008.
- 318 See 42 U.S.C. § 1396d and 42 C.F.R. § 1001.952(w).
- 319 See 42 C.F.R. § 1001.952(w).
- 320 See OIG Advisory Opinion No. 08-01 (January 28, 2008) and OIG Advisory Opinion No. 06-08 (June 27, 2006).
- 321 See 42 C.F.R. § 1001.952.
- 322 U.S. Dep't of Health and Human Servs, Ctrs. For Medicare & Medicaid, *Clinic Laboratory Improvement Amendments–How to Obtain a CLIA Certificate*, (2003). *available at* https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/HowObtainCLIACertificate.pdf.
- 323 U.S. Dep't of Health and Human Servs. U.S. Food and Drug Admin., *CLIA-Clinic Laboratory Improve-ment Amendments-Currently Waived Analytes*, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/analyteswaived.cfm.
- Devery Howerton et al., Good Laboratory Practices for Waived Testing Sites: Survey Findings from Testing Sites Holding a Certificate of Waiver Under the Clinic Laboratory Improvement Amendments of 1988 and Recommendations for Promoting Quality Testing, MMWR, (Nov. 2005) available at http://www.cdc.gov/mmwr/pdf/rr/rr5413.pdf.
- 325 Gayle Goldin & Sarah Hanson, *Starting a Free Clinic: A Volunteers in Health Care Guide.* Volunteers in Health Care (2002), http://www.nafcClinics.org/sites/default/files/resources/start%20a%20free%20Clinic.pdf.
- Lindsey, J. Stephen and John Rawles, III, 5 Ways Hospitals Can Partner With Free Clinics, February 5, 2013, Becker's Hospital Review. Available at http://www.beckershospitalreview.com/strategic-planning/5-ways-hospitals-can-partner-with-free-clinics.html.
- 327 See Goldin & Hanson, supra.
- 328 See Goldin & Hanson, supra.
- 329 United Way Worldwide, Our Work, United Way, http://www.unitedway.org/our-work (last visited July 10, 2014).
- 330 See, Interview with Judith Hassis, supra.
- 331 U.S. Department of Labor, *Occupational Safety & Health Administration*, OSHA, https://www.osha.gov/workers.html (last visited July 10, 2014).
- 332 U.S. Department of Labor, Occupational Safety & Health Administration (OSHA), *Know Your Rights*, https://www.osha.gov/workers.html.
- 333 U.S. Department of Labor, OSHA, *Workplace Violence: OSHA FACT Sheet,* (2002), https://www.osha.gov/OshDoc/data General Facts/factsheet-workplace-violence.pdf.
- 334 See U.S. Department of Labor, OSHA, Worplace Violence, supra.
- I Evelyn Bain, *Workplace Violence: New standard set after MNA nurses advocate for metal detectors in their facilities*, Massachusetts Nurses Ass'n, (Feb. 15, 2007), http://www.massnurses.org/health-and-safety/articles/workplace-violence/p/openItem/1310.; John Pirro, *Hospital violence becoming an epidemic, security experts say*, newstimes.com, (Mar. 29, 2010), http://www.newstimes.com/news/article/Hospital-violence-becoming-an-epidemic-security-427025.php.
- 336 U.S. Dep't of Justice Office of Justice Programs, *Walk-Through Metal Detectors for Personnel*, ncjrs.gov, https://www.ncjrs.gov/school/ch3a_5.html (last visited July 10, 2014).
- Chris Richard, *Metal detectors to be removed at most county facilities*, California Health Report (Feb. 25, 2013), http://www.healthycal.org/metal-detectors-to-be-removed-at-most-county-medical-facilities/.
- 338 Telephone Interview with Debbie Megan, Dir., Brandon Outreach Clinic (July 18, 2014).

Factoid Sources

Page	
23	National Association of Free and Charitable Clinics http://www.nafcclinics.org/resources/infographic
30	HealthRight 360 http://www.healthright360.org/about
33	National Association of Free and Charitable Clinics http://www.nafcclinics.org/resources/infographic
39	National Association of Free and Charitable Clinics http://www.nafcclinics.org/resources/infographic
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63	National Association of Free and Charitable Clinics http://www.nafcclinics.org/sites/default/files/
	NAFC%20ACA%20Related%20Talking%20Points%202015.pdf
68	National Association of Free and Charitable Clinics http://www.nafcclinics.org/resources/infographic
70	National Association of Free and Charitable Clinics http://www.nafcclinics.org/resources/infographic
77	Virginia Association of Free and Charitable Clinics http://www.vafreeclinics.org/
85	Gary Burnstein Community Health Center, Michigan https://www.garyburnsteinclinic.org/
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	ics.org/files/assets/IAFCC%202014%20Statewide%20Survey%20Report%20FINAL%20SPREADS.pdf
97	Brooklyn Free Clinic http://www.brooklynfreeclinic.org/community/
101	Fan Free Clinic http://www.fanfreeclinic.org/about-us/mission-history/
109	Milan Puskar Health Right Clinic http://www.mphealthright.org/
113	Pocatello Free Clinic http://www.pocatellofreeclinic.com/press/annualreport/AnnualReport2013.pdf

Authors and Contributors

The American Health Lawyers Association is grateful to **Peter A. Pavarini** of Squire Patton Boggs (US) LLP for his vision and leadership, which made this project possible, and to **Mark A. Kadzielski** of Pepper Hamilton LLP and **John R. Holdenried** of Baird Holm LLP for their valuable contributions as chief editors and peer reviewers of this publication. Peter, Mark, and John's commitment to serving indigent communities and improving the lives of families in need is unparalleled and sets an example for all of us. Peter can be reached at peter.pavarini@squirepb.com; Mark can be reached at kadzielskim@pepperlaw.com; and John can be reached at jholdenried@bairdholm.com.

AHLA specially recognizes **Jennifer C. Hutchens** and **Rachel D. Ludwig** for their work in editing and coordinating the publication, as well as their strategic insight and vision for the guidebook.

Jennifer C. Hutchens is a Shareholder at Robinson Bradshaw & Hinson PA, Charlotte, NC, practicing in the Corporate and HealthCare Group. She can be reached at jhutchens@rbh.com.

Rachel D. Ludwig is an Associate at Jackson Kelly PLLC, Charleston, WV, practicing in the Health Care and Finance Practice Group. She can be reached at rdludwig@jacksonkelly.com.

AHLA thanks the following authors for their contributions. **Special recognition*** is given to those who assisted in coordinating and editing the content of their respective workgroups.

Molly R. Berkery* is an Associate at Godfrey & Kahn SC, Green Bay, WI, practicing in the Health Care Practice Group. She can be reached at mberkery@gklaw.com.

Kristen R. Blanchette is an Associate at Davis Wright Tremaine LLP, Los Angeles, CA, practicing in the Health Law Group. She can be reached at kristenblanchette@dwt.com.

Michael W. Chase is an attorney at Baird Holm LLP, Omaha, NE, practicing in the Health Care Group and the Privacy & Data Protection Group. He can be reached at mchase@bairdholm.com.

Richard Y. Cheng is a Partner at Shannon Gracey Ratliff & Miller LLP, Dallas, TX, where he co-heads the firm's Healthcare Practice Group. His health law practice has a particular emphasis on representing post-acute care, rehabilitation and ancillary health care providers. He can be reached at rcheng@shannongracey.com.

Samantha M. Collado is, at the time of publication, a 2016 J.D. candidate at the University of Maryland, Francis King Carey School of Law. She received her Master of Public Health from Emory University and her B.A. in Public Health from Johns Hopkins University. She can be reached at scollad1@gmail.com.

Lara D. Compton is an Associate at DLA Piper, San Francisco, CA, practicing in the Healthcare Group with a focus on HIPAA and Privacy. She can be reached at lara.compton@dlapiper.com.

Meaghan Mary Cooper is an Associate at Robinson & Cole LLP, Hartford, CT, practicing in the Health Law Group. She can be reached at mcooper@rc.com.

Lauren A. DeWitt is an Associate at Pepper Hamilton LLP, Philadelphia, PA, practicing in the Corporate and Securities Practice Group. She can be reached at dewittl@pepperlaw.com.

Thomas (T.J.) Ferrante is an Associate at Carlton Fields Jorden Burt PA, Tampa, FL, focusing on a wide range of transactional and related regulatory issues for health industry clients. He can be reached at tferrante@cfjblaw.com.

Lisa Gora* is an Associate at Wilentz Goldman & Spitzer PA, Woodbridge, NJ, practicing in the Business Law and Health Care Teams. She can be reached at lisagora@wilentz.com.

Lane Greer is Chief Legal Counsel at CommUnityCare, Austin, TX. She can be reached at lane.greer@communitycaretx.org.

Lindsay P. Holmes is an Associate at Baker Hostetler, Washington, DC and practices in regulatory and transactional health care matters. She can be reached at lholmes@bakerlaw.com.

Jennifer Wooten Ierardi* serves as the Chief Integrity Executive at Northwestern Memorial HealthCare, Chicago, IL, with responsibility for general corporate compliance and privacy, billing compliance and enterprise risk management. She can be reached at jwooten@nm.org.

Sarah Jordan is In-House Counsel for Palomar Health, a public health district in Southern California. She can be reached at sarah.jordan@palomarhealth.org.

Alex T. Krouse is an attorney at Krieg DeVault LLP, Indianapolis, IN, practicing on the Health Care and Business Practice Teams. He provides corporate, regulatory, and transactional advice to a variety of clients in the health care industry. He can be reached at akrouse@kdlegal.com.

Xavier Lawrence is, at the time of publication, a third year law student at Columbia Law School. He was also a 2014 Summer Associate at Husch Blackwell LLP, Kansas City, MO. He can be reached at xql2000@columbia.edu.

Amanda Leipold is a Compliance Attorney at Dean Health Plan, Madison, WI. She can be reached at amandaleipold@gmail.com.

Lisa M. Luetkemeyer is a Member of Husch Blackwell LLP, St. Louis, MO, practicing on the Healthcare, Life Sciences & Education Team and provides regulatory guidance to a variety of clients in the health care industry. She can be reached at lisa.luetkemeyer@ huschblackwell.com.

Stanford L. Moore is an Associate at Squire Patton Boggs (US) LLP, Columbus, OH, practicing in the Health Care Practice Group. He can be reached at stanford.moore@squirepb.com.

Beatrice M. Nokuri is an Associate at Bricker & Eckler LLP, Columbus, OH, practicing in the Health Care Group. She can be reached at bnokuri@bricker.com.

Marilyn Coleman Robertson is an Associate at Husch Blackwell LLP, Austin, TX, practicing on the Healthcare, Life Sciences & Education Team. She can be reached at marilyn.robertson@huschblackwell.com.

Cara Rose Tucker is an attorney living in Charlotte, NC. She works with the Garretson Resolution Group in health care lien resolution. She can be reached at crmtucker@gmail.com.

Kelly E. Schulz* is an Associate at Polsinelli, Kansas City, MO, assisting a broad range of health care organizations in criminal and civil investigations and regulatory compliance matters. She can be reached at kschulz@polsinelli.com.

Wakaba Y. Tessier is an Associate at K & L Gates, Seattle, WA where she represents providers, pharmacies, and other health care entities on various regulatory compliance issues. She can be reached at wakaba.tessier@klgates.com.

Erdal Turnacioglu* is an Associate at Weber Gallagher, Warren, NJ, concentrating on general liability, medical malpractice, and commercial litigation matters. He can be reached at eturnacioglu@wglaw.com.

Cori Casey Turner is a Partner at Husch Blackwell LLP, Kansas City, MO, practicing in the Healthcare, Life Sciences & Education Team, focusing primarily on compliance, reimbursement, and physician affiliation matters. She can be reached at cori.turner@huschblackwell.com.

Kimela R. West is Associate Counsel at Mercy Health East Communities, St. Louis, MO. She can be reached at kimela.west@mercy.net.

Dennis Williams* is an Associate at DLA Piper, Miami, FL, where his primary focus is on health care transactional, regulatory, and enforcement matters. He can be reached at dennis.williams@dlapiper.com.

Stephanie D. Willis* is an Associate at Crowell & Moring, Washington, D.C., practicing in the Health Care Group. She can be reached at swillis@crowell.com.

Rachel Yount is a Compliance Consultant Attorney at Sentara Healthcare, Norfolk, VA, practicing in health care regulatory compliance. She can be reached at reyount@sentara.com.

Special Thanks to our Public Interest Donors

The Legal and Operational Guide for Free Medical Clinics was made possible by the generosity of the American Medical Association Foundation and AHLA's Public Interest Donors.

AHLA's Public Interest Donors contributing \$100 or more between January 1, 2014 and May 31, 2015 are recognized here for their support in helping turn the idea of this guidebook into a reality. For the complete list of all AHLA Public Interest Donors, please visit www.healthlawyers.org/donors.

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