

K&L GATES

TRIAGE: RAPID LEGAL LESSONS FOR BUSY
HEALTH CARE PROFESSIONALS



Triage in 2020:
Health Care Topics to Watch in the New Year

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HEALTH CARE TOPICS TO WATCH IN 2020

- For the fourth season of Triage, we have compiled the following lists of topics that we believe will have the greatest impact on the health care industry in the coming year
- K&L Gates will continue to monitor topics in these areas and others and provide timely updates via Triage and Client Alerts in 2020

2020 PRESIDENTIAL CAMPAIGN AND LEGISLATION

- Health care to be defining issue for a number of candidates and voters
- Thirteen Democratic candidates on ballot, each with own plan for U.S. health care system
- Price transparency
- Surprise billing legislation
- Drug pricing reform
- Access to rural health care

OPIOID CRISIS

- Implementation of SUPPORT Act
- PFS Final Rule for Calendar Year 2020 creating new benefit category allowing OTPs to bill and receive payment under Medicare program
- Bundled payment rates for OUD services furnished by an OTP
- Bundled payment rates for OUD services furnished by clinician in office-based setting

340B DRUG DISCOUNT PROGRAM

- OPSS for Calendar Year 2020 finalizing proposal to pay adjusted amount of ASP minus 22.5 percent
- Uncertainty due to U.S. District Court for District of Columbia ruling that Secretary exceeded his authority to adjust payment rates
- Ruling appealed to Court of Appeals for the D.C. Circuit
- CMS has collected survey data, which may be utilized to promulgate a new, future reimbursement cut, but also to potentially justify the conclusion that no remedy is owed to 340B hospitals for 2018 and 2019.

HHS PROPOSED VALUE-BASED ANTI-KICKBACK AND STARK EXCEPTIONS

Agency	Limited Risk Share	Significant Risk Share	Full Risk Share
OIG/AKS Safe Harbor	"Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor"	"Value-Based Arrangements with Substantial Downside Financial Risk"	"Value-Based Arrangements With Full Financial Risk"
CMS/Stark Exception	"Value-Based Arrangements"	"Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician"	"Full Financial Risk"

HHS PROPOSED RULE FOR STARK LAW

- 2019 Proposed Rule to be finalized in 2020
- Compensation takes referrals into account only when the mathematical formula used to calculate the compensation includes the number of referrals as a variable and the amount of compensation correlates with physician's referrals
- Productivity bonuses will not take into account volume or value of referrals solely because corresponding hospital services are billed each time physician performs a service.
- Direct response to *United States ex rel. Drakeford v. Tuomey Healthcare Systems, Inc.*

FRAUD AND ABUSE LANDSCAPE

- 2019 saw government enforcement surrounding marketing and telemedicine in DME and genetic cancer screening arenas
- Operations Brace Yourself and Double Helix amounted to two of the largest health care fraud takedowns in U.S. history
- In 2020, we expect heavy scrutiny of telemedicine and marketing arrangements to expand to the use of telemedicine in other arenas, including pharmaceutical sales and activities
- Expect continued enforcement to combat opioid crisis
- 2020 may include increased qui tam filings involving physician compensation arrangements in light of *U.S. ex rel. J. William Bookwalter, III. M.D. et al. v. UPMC et al.*

RETAIL HEALTH

- Industry is responding to patient demand by adding service options in retail space, for example retail clinics in local drug stores
- Proponents suggest treatment in retail locations may lead to decline in costs and limit ER visits
- Regulatory shifts towards interoperability and price transparency support retail model and ease of access to health information and treatment for patients

DIGITAL HEALTH

- Market innovators and health systems to face pressing questions surrounding use of AI
- Legislators to take close look at interoperability, especially pertaining to implementation of 21st Century Cures Act
- CMS Proposed Rule for Donation of Cybersecurity Technology
- Emerging use of telemedicine anticipated, especially for primary care in rural settings

MERGERS AND ACQUISITIONS

- Private equity has ruled over last fifteen years, with role in health care increasing and results outperforming overall market
- Days of pure community-based organizations are ending, with multi-state, multi-market operators coming into play
- Heightened anti-trust enforcement from state Attorney Generals in light of greater health system mergers

Today's Presenter



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