Morgan Lewis

FAST BREAK: REGULATORY SPRINT PART 2

Katie McDermott, Matt Hogan, and Jake Harper

November 20, 2019

WEBINARS

FAST BREAK WEBINAR SERIES

2019

Our *Fast Break* series features monthly healthcare-focused webinars. These 45-minute webinars explore important developments, trends, and hot topics in the healthcare industry in an easy-to-digest format.

Hosted by Jake Harper, each program is joined by an industry topic leader to cover a wide range of topics geared toward lawyers and specialists who handle healthcare-related matters.

Register for the next *Fast Break*

Regulatory Sprint Part 2
November 20, 2019

2019

Fast Break: Regulatory Sprint Part 1
October 30, 2019
Listen to recording >>
View the slides >>

Fast Break: *Aseracare*
September 26, 2019
Listen to recording >>
View the slides >>

OUR PARTICIPANTS

JACOB J. HARPER
ASSOCIATE
Washington, DC

RESOURCE

LEARN MORE ABOUT OUR WORK IN THE HEALTHCARE SECTOR >>

Agenda

- New AKS safe harbors for protecting arrangements between healthcare providers for value-based care
- The game-changing role of social determinants of health in value-based care and certain safe harbor proposed amendments
- OIG's uncertainty and request for input on patient engagement and incentives provides rare opportunities

AKS Proposed Rule At-A-Glance

- New Safe Harbor for value-based arrangements;
- New Safe Harbor for VBA related patient engagement tools and support;
- New Safe Harbor related to donation of cybersecurity technologies;
- Modifications to EHR safe harbor related to interoperability;
- Expanding personal services safe harbor for outcomes-based payments and part-time arrangements;
- Expanding local transportation safe harbor for mileage ranges but also for hospital discharged patients;
- Expanding permitted beneficiary inducements to telehealth technologies provided to provide in-home dialysis patients.

VBE Theory

- Both CMS and OIG approach value-based regulations the same way:

Proposes Rules for Regulatory Sprint

- OIG rule, more so than CMS rule discussed last month, is bifurcated
  - AKS focus on provider-to-provider relationships
  - CMP focus on provider-to-patient relationships

- AKS portion of rule largely reflects same basic considerations as CMS rule
  - But some notable differences:
    - AKS rule is more restrictive than Stark Law equivalent
    - Requirements for Care Coordination Agreements as minimal threshold for protections

New AKS Safe Harbor

- New safe harbors for participants in "value-based arrangements" including
  - care coordination arrangements
  - value-based arrangements with substantial downside financial risk, and
  - value-based arrangements with full financial risk

- Safe harbors will allow the exchange of remuneration within these arrangements in a similar manner to ACOs and other savings-based arrangements

- Compliance with safe harbor may be important gateway to offering protected patient incentives

Patient Incentives

- New safe harbor related to patient engagement tools
  - Must be in a value-based arrangement to promote better outcomes and efficiencies
  - Patients to whom support is offered must be part of a "target population"
  - Only in-kind support permitted with an annual aggregate value of $500
    - No cash/cash equivalents and no waiver of cost-sharing obligations

- Those who offer such tools must be part of a "value-based enterprise" (VBE)
  - Certain stakeholders expressly excluded, including labs, DMEPOS supplies, pharma, and distributors

Social Determinants of Health

- Important new conceptual framework introduced in proposed rule for VBE arrangements and local transportation, both in unique ways.
- Should support incentives address social determinants of health?
  - Nutrition
  - Housing
  - Transportation
  - Other obstacles to medical management or healthcare equity
- Could focus on these non-medical factors of a patient's overall health status be a game changer?

Personal Services Safe Harbor Amendment

- Personal services safe harbor proposed amendment provides that the definition of remuneration not include compensation related to outcomes based payments.
- Must meet several requirements, including requirements similar to the safe harbor related to prohibiting compensation for volume and value of referrals.
- Arrangement must relate to improving patient care and reducing costs based upon clinical evidence and medical support.
- Outcomes based payments limited from principal to non-employee agent as reward for improving patient or population health by reaching one or more outcomes that effectively manage care across different care settings.
- Pharmaceutical manufacturer, distributor or supplier of DME or prosthetics or labs not excluded for outcomes based payments.

Do These Proposals Go Far Enough?

- OIG proposal on patient incentives:
  - Does not include cash, coupons, and cash equivalents
  - Long-studied effective mechanism to induce/maintain compliance with treatment protocols
  - Seeks input on whether to expand to other incentives
  - Social determinants of health are big area to consider patient incentives and engagement

What To Do Next

- **Comment**
  - Although these rules reflect substantive reforms, CMS and OIG appear open to healthcare stakeholders' opinions
  - The agencies consistently request input from the provider community, which suggests that stakeholders have the ability to influence the final rules
  - Evaluate the impact the proposed rules might have on your organization and its future plans and assess how changes to these proposals could be beneficial
- **Collaborate**
  - Value-based arrangements promote collaborative arrangements between patients, physicians, hospitals, and other healthcare providers
  - CMS and OIG have shown no signs of backing off of value-based models so it is likely an eventuality for all providers
  - Developing clinically integrated networks and value-based arrangements now may lead to competitive advantages in the near- and long-term

Thanks!

Katie McDermott
Partner
Washington, DC
+1.202.739.5458
kathleen.mcdermott@morganlewis.com
Click Here for full bio

A former Assistant US Attorney and US Department of Justice (DOJ) Healthcare Fraud Coordinator, Katie McDermott represents healthcare and life sciences clients throughout the United States in government investigations and litigation matters relating to criminal, civil, and administrative allegations, including violations of the False Claims Act and its whistleblower provisions. Katie also advises on corporate compliance matters relating to internal investigations, voluntary government disclosures, consent decrees, and corporate integrity agreements.

Thanks!

Matt Hogan
Partner
Philadelphia
+1.215.963.5254
matthew.hogan@morganlewis.com
Click Here for full bio

Matthew J.D. Hogan brings his experience as a former federal prosecutor to his representation of clients in connection with government investigations and white collar defense. Matt's practice focuses on assisting organizations and individuals targeted in government investigations and related litigation. He represents clients in a wide array of white collar matters, internal investigations, False Claims Act litigation, and other complex matters involving federal and state investigations and litigation. He has worked with boards of directors, audit committees, and corporate leadership to conduct internal investigations and he is an active member of the firm’s crisis management practice.

Thanks!

Jake Harper
Associate
Washington, DC
+1.202.739.5260
jacob.harper@morganlewis.com
Click Here for full bio

Jacob Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.

Join us next month!

Please join us for next month's webinar:

"A *Fast Break* Year in Review"

Featuring Jake Harper and Dani Elks

- December 18 at 3:00 PM (EST)