

# Four Hot Topics in Health Law

Dan Glessner, Esq.

Laura Fryan, Esq.



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## PRICE TRANSPARENCY

1. Ohio: House Bill 52 and Senate Bill 97
2. Federal level: CMS 1717 (Final) and CMS-9915 (Proposed)



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# 1. Ohio: Third Time's a Charm or Three Strikes and You're Out?

## Ohio House Bill 52

Mandated that, prior to providing services, providers provide good-faith estimate of:

- (1) amount provider would charge patient's health plan
- (2) amount the health plan intended to pay, and
- (3) the difference, if any, the patient would be required to pay.

### Attempt 1:

- Attached last-minute to Worker's Compensation bill
- Simple/short, few details or enforcement mechanisms
- Court orders injunction (Dec. 2016)
- Bill sponsor State Rep. Jim Butler (R-Oakwood) filed to intervene

### Attempt 2:

- Gov. DeWine vetoed 2<sup>nd</sup> pass at bill (Sept. 2019)

*Ultimately defeated on procedural grounds (Feb. 2020)*



## Ohio Senate Bill 97

### Attempt 3:

- Passed unanimously in the Senate (Oct. 2019)
- Introduced in the House and referred to Health Committee (Oct. 2019)
- Requires hospitals to furnish a good-faith estimate of prices a patient is expected to pay at least 7 days before services are rendered, if the patient asks



## 2. Federal: Hospitals and Insurers

**Hospitals:** must publish “standard charges” and shoppable services by January 1, 2021

*Industry groups and hospitals filed suit December 2019, plaintiffs and defendant both filed motions for summary judgment, April 22<sup>nd</sup> hearing date*

**Insurers:** proposed rule requires-

- Personalized out-of-pocket cost information for all covered health care items and services
- Publication of the negotiated rates with in-network providers online, as well as a history of the payments allowed to out-of-network providers



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## DATA PROTECTION

1. State level: Ohio
2. State level: California
3. International: GDPR



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## 1. State Level: Ohio

### Ohio Data Protection Act (ODPA)

- Incentivize robust cybersecurity
- Requires reasonable conformity to industry norms for cybersecurity
- Provides affirmative defense for covered entities against data breach tort claims
- Requirements vary by entity's size and scope, activities, sensitivity of information, and resources.



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## 2. State Level: California

### California Consumer Privacy Act

- A right to:
  - Know what information is collected/shared/sold
  - Delete personal information
  - Opt out of data collection
  - Non-discrimination for exercise of these rights.



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1798.145:

(c) (1) This title shall not apply to any of the following:

(A) Medical information governed by the Confidentiality of Medical Information Act (Part 2.6 (commencing with Section 56) of Division 1) or **protected health information that is collected by a covered entity or business associate governed by the privacy, security, and breach notification rules issued by the United States Department of Health and Human Services...**

(B) A provider of health care governed by the Confidentiality of Medical Information Act (Part 2.6 (commencing with Section 56) of Division 1) **or a covered entity governed by the privacy, security, and breach notification rules issued by the United States Department of Health and Human Services...to the extent the provider or covered entity maintains patient information in the same manner as medical information or protected health information as described in subparagraph (A) of this section.**

(C) **Information collected as part of a clinical trial...**

(2) For purposes of this subdivision, the definitions of "medical information" and "provider of health care" in Section 56.05 shall apply and the definitions of "business associate," "covered entity," and "protected health information" in Section 160.103 of Title 45 of the Code of Federal Regulations shall apply.



## Warning:

- Check an organization's status under HIPAA, and the purpose for which the organization collects data
- Unclear whether subsection (B) exempts all of a covered entity/business associate's data
- CCPA considered a model for other state/federal legislation

*Fuentes v. Sunshine Behavioral Health Group, LLC* (Case No. 8:20-cv-00487, Central District of California)



### 3. International: GDPR

#### General Data Protection Act

- Broad law affecting members of European Union implemented in 2018
- Requires:
  - Transparency in data processing,
  - Minimizing processing and limit collection to minimum amounts for legitimate purposes explicitly specified
  - Maintenance and accuracy of personal data
  - Limiting time data is stored
  - Secure and confidential processing of data
  - Accountability to demonstrate compliance with the law.



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## PROVIDER-BASED RULES

1. Ohio Ambulatory Surgery Facility Licensing
2. Federal Site Neutrality



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# 1. Ohio Ambulatory Surgery Facility Licensing

- On July 18, Governor DeWine signed HB 166, the \$69 billion two-year state operating budget
- The ASF changes were proposed in the Governor's original budget and remained unchanged throughout the process.
- The ASF changes were effective October 17, 2019 and modified the definition of an ambulatory surgery facility in Ohio Revised Code 3702.30(A)(1) –

*"Ambulatory surgical facility" means a facility in which surgical services are provided to patients who do not require hospitalization for inpatient care, the duration of services for any patient does not extend beyond twenty-four hours after the patient's admission, and to which any of the following apply:*

*(a) The surgical services are provided in a building that is separate from another building in which inpatient care is provided, regardless of whether the separate building is part of the same organization as the building in which inpatient care is provided.*



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# 2. Federal Site Neutrality

- In November 2018, CMS finalized "site neutrality" in the Medicare Hospital Outpatient Prospective Payment System (OPPS)
- Site Neutrality = The final 2019 OPPS rule lowered the payment for clinic visits at provider-based offices to the equivalent payment under the Medicare Physician Fee Schedule with a two-year phase-in approach

Example: HCPCS code G0463 (hospital outpatient clinic visit for assessment and management of a patient)

- 2019- reimbursement at 70% of the OPPS rate
- 2020- reimbursement at 40% of the OPPS rate

Before 2019, the OPPS rate for a clinic visit was approximately \$116 with \$23 being the average beneficiary copayment. The adjustment down to the Medicare Physician Fee Schedule equivalent rate in 2020 reduces the payment to \$46 and a beneficiary copayment of \$9



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- September 2019: the US Court for the District of Columbia struck down the 2019 final rule
- November 2019: CMS continued to phase in site-neutral rates as part of the two-year plan starting January 1, 2020. CMS said in December 2019 that it is working to reprocess claims paid to affected hospital clinics to repay hospitals \$380 million in cuts for the 2019 year.
- January 2020: hospital industry groups sued HHS again to stop the 2020 cuts

## CHANGES TO THE STARK LAW AND ANTI-KICKBACK STATUTE

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1. OIG changes to the Anti-Kickback Statute
2. CMS changes to Stark Law



## 1. Anti-Kickback Statute

What's new:

OIG proposed new safe harbors under the Anti-Kickback Statute including:

- Three new safe harbors for value-based arrangements and care coordination services
- Safe harbors for patient engagement tools or supports, CMS Innovation Models, and donation of cybersecurity technology and services



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Modifications to current safe harbors:

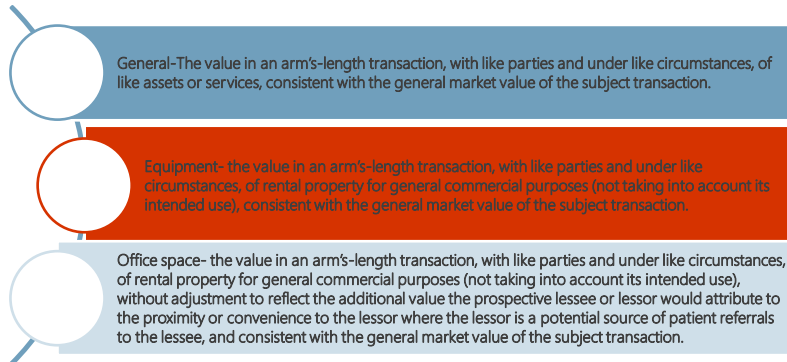
- EHR
- Personal services and management
- Warranties
- Local transportation
- Codify exception to remuneration for beneficiaries participating in ACO



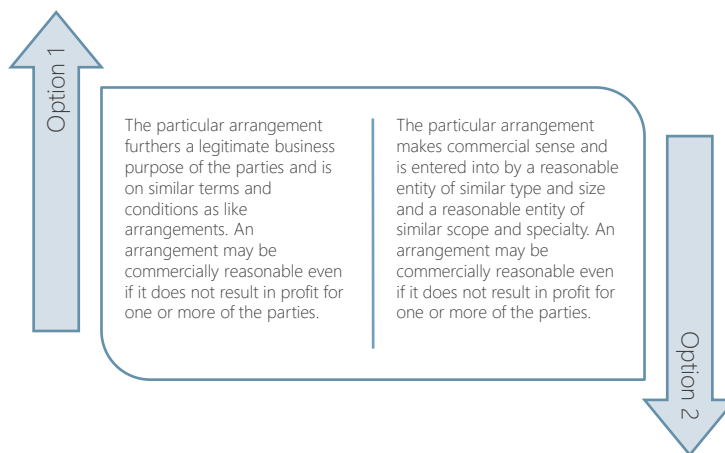
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## 2. Stark Law

### A. Fair Market Value (42 C.F.R. § 411.351)



### B. Commercial Reasonableness



### C. Volume or Value

- Attempt at a bright line rule
- Separate standards for compensation TO a physician and FROM a physician



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## Questions?

Dan Glessner

[Dglessner@Brouse.com](mailto:Dglessner@Brouse.com)

Laura Fryan

[Lfryan@Brouse.com](mailto:Lfryan@Brouse.com)



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