

Owning an Opportunity - Digital Health Developments for 2021

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AGENDA

- ❖ **National Regulatory Trends**
 - year in review and what lies ahead
- ❖ **State Regulatory Developments**
 - including Massachusetts telehealth legislation
- ❖ **Anti-Kickback Statute/Stark Law Value-Based Arrangements**
- ❖ **DTC Growth – Opportunities and Risks in Innovation**
- ❖ **Q&A**

NATIONAL REGULATORY TRENDS – YEAR IN REVIEW, AND WHAT LIES AHEAD

National Regulatory Trends

- ▶ The COVID-19 pandemic catapulted telehealth forward.
- ▶ Medicare abandoned or modified restrictions on “Medicare telehealth services.”
- ▶ Temporary breathing room on HIPAA, Beneficiary Inducement Law, Stark.

National Regulatory Trends

- ▶ Modality Restrictions Lifted
- ▶ Eligible Providers Expanded
- ▶ Originating Site Restriction Abandoned (including rural HPSA requirement)
- ▶ Eligible Services Expanded

National Regulatory Trends

- ▶ Is any of this actually permanent?
- ▶ COVID waivers in place until PHE ends or end of CY 2021 (whichever is later)
- ▶ 2021 Physician Fee Schedule
- ▶ Remember Medicare Advantage?
- ▶ What will Congress do?

STATE REGULATORY DEVELOPMENTS, INCLUDING MASSACHUSETTS TELEHEALTH LEGISLATION

State Regulatory Developments

- ▶ During PHE, every state medical board adopted regulatory flexibility.
- ▶ State Medicaid programs largely followed Medicare's lead.
- ▶ Coverage and payment parity in commercial markets.
- ▶ ULC Model Telehealth Laws → consensus?

State Regulatory Developments

State	COVID License Waiver?	Waiver/PHE Duration	Current Status
Massachusetts	Temporary licenses were issued until mid-2020.	PHE terminates 6/15/2021.	Temporary licenses will soon be invalid.
Maine	Emergency license available to qualified out of state physicians.	PHE in place until at least 6/12/2021.	Emergency licenses remain effective.
Connecticut	Licensure requirement waived during CT PHE and 2 years thereafter.	License waiver in place until June 2023.	License waiver effective for (at least) two more years.
New York	License requirement waived through end of New York PHE.	NY PHE most recently extended through 6/24/21.	License waiver currently effective.
Florida	License requirement waived for up to 30 days of treatment for established patients during PHE.	PHE was most recently extended through 6/26/21.	License waiver currently effective for established patients.

State Regulatory Developments

- ▶ Volume and speed in state-level developments not seen since 2014-2016.
- ▶ Coverage and payment parity provisions.
- ▶ Modality-agnostic telehealth definitions.
- ▶ What are payors and health systems saying?

State Regulatory Developments

- ▶ BORIM Policy.
- ▶ Technology-agnostic telehealth definition.
- ▶ Coverage and payment parity for behavioral health, primary care (temporarily).
- ▶ Further DOI regulations expected Fall 2021.

ANTI-KICKBACK STATUTE AND STARK LAW – VALUE-BASED ARRANGEMENT SAFE HARBORS/EXCEPTIONS

Value-Based Arrangements – New Safe Harbors/Exceptions

- ▶ **Anti-Kickback Statute (AKS) and Federal Physician Self-Referral Law (Stark Law)**
 - 30,000 foot level
- ▶ **Final Rules Effective Jan. 19, 2021**
 - Part of HHS Regulatory Sprint to Coordinated Care
 - HHS aims to improve patient experience, provider care coordination, and information sharing
 - Significant New and Modified Safe Harbors/Exceptions

Value-Based Arrangements – New Safe Harbors/Exceptions

▶ **Goals of the Rules**

- Remove regulatory barriers to innovation
- Encourage participation in value-based arrangements
- Clarification/simplification of existing rules

▶ **Concern that AKS and Stark have had a “chilling effect on innovation and value-based care”**

Value-Based Arrangements – New Safe Harbors/Exceptions

- ▶ OIG Recognizes Importance of Digital Health
- ▶ “[D]igital health companies hold great promise for improving coordination and management of care and achieving the goals of the Regulatory Sprint”
- ▶ “Flexibilities to engage in new ... digital health technology arrangements with lowered compliance risk may assist industry stakeholders in their response to and recovery from the current [COVID-19] pandemic”

Value-Based Arrangements – New Safe Harbors/Exceptions

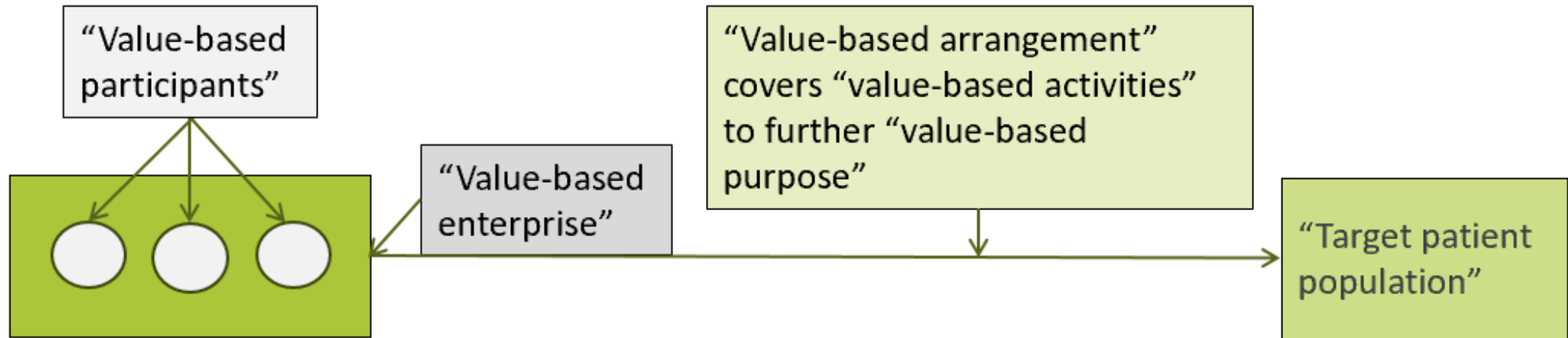
- ▶ **3 New AKS Safe Harbors (3 New Stark Law Exceptions) protecting remuneration between participants**



- ▶ **1 New AKS Safe Harbor protecting remuneration to beneficiaries**

Value-Based Arrangements – New Safe Harbors/Exceptions

► What is a Value-Based Arrangement?



Value-Based Arrangements – New Safe Harbors/Exceptions

- ▶ **Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor – No Downside Risk Required**
 - In-kind remuneration – recipient pays at least 15% of cost or FMV
 - Predominantly to engage in value-based activities
 - Directly connected to coordination and management of care of the target patient population
 - Commercially reasonable
 - Signed writing, set in advance
 - Establish (and monitor and revise, as necessary) legitimate outcome or process measures

Value-Based Arrangements – New Safe Harbors/Exceptions

▶ Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor – Certain Key Restrictions

- No more than incidental benefits to other patients
- Remuneration not for marketing or patient recruitment
- Doesn't take into account volume or value of referrals outside of TPP
- No directed referrals if other patient choice, payor determination, or professional judgment
- No inducement to furnish medically unnecessary items/services or reduce medically necessary services
- Doesn't protect remuneration from certain entities, with limited exceptions

Value-Based Arrangements – New Safe Harbors/Exceptions

▶ Care Coordination Safe Harbor – Digital Health Examples

- Hospital provides RPM technology to physician practice for patients post-discharge
- Tech company provides digitally equipped devices to physician practice for patients post-discharge
- Specialty physician practice provides data analytics software and services to primary care practice from which it receives referrals for consultations

Value-Based Arrangements – New Safe Harbors/Exceptions

▶ Care Coordination Safe Harbor – Digital Health Examples (continued)

- Hospital provides tablets to physician group for in-office patient education
- Device manufacturer* of cardiac monitoring devices provides software solution for use between hospital and EMS

*Additional limitations apply for medical device/supply manufacturers or distributors

Value-Based Arrangements – New Safe Harbors/Exceptions

▶ Patient Engagement Tools and Supports Safe Harbor

- New safe harbor available to value-based enterprise
- Protects in-kind remuneration to patients in a target patient population - \$500 annually
- Must be connected to coordination and management of care and meet other requirements
- Must be recommended by licensed health care professional
- Similar restrictions (e.g., not used for marketing/recruitment)

Value-Based Arrangements – New Safe Harbors/Exceptions

- ▶ **Patient Engagement Tools and Supports Safe Harbor – Digital Health Examples**
 - RPM device
 - Broadband access to enable RPM or virtual care
 - Connected scales or blood pressure monitors that track and transmit data to a professional
 - Applications that allow a patient's mobile devices to monitor activity or other health data
 - Device that reminds a patient to take a medication or attend a scheduled office visit

Value-Based Arrangements – New Safe Harbors/Exceptions

► Things to keep in mind:

- State Law
- Non-profit, tax-exempt considerations

DTC EXPONENTIAL GROWTH – OPPORTUNITIES AND RISKS IN INNOVATION

DTC Growth – Opportunities and Risks in Innovation

- ▶ Explosive growth in digital health investment a bubble or “new normal?”
- ▶ Uptick in interest in platforms offering specialty services.
- ▶ What role will brick and mortar providers play, if any?

DTC Growth – Opportunities and Risks in Innovation

- ▶ **Increased Attention and \$\$ → Increased Enforcement Scrutiny**
- ▶ **Suggested areas of compliance focus:**
 - Financial relationships with referral sources
 - Payor reimbursement rules
 - Patient privacy and security
 - Corporate practice of medicine
 - Scope of practice/license requirements
 - Consent
 - Patient choice

DTC Growth – Opportunities and Risks in Innovation

- ▶ Why isn't expanded Medicare coverage permanent?
- ▶ Understanding Telehealth v. Telefraud

Thank you.

Q&A