Owning an Opportunity - Digital Health Developments for 2021

Amy M. Joseph and Jeremy D. Sherer
June 10, 2021
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
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?
<table>
<thead>
<tr>
<th>State</th>
<th>COVID License Waiver?</th>
<th>Waiver/PHE Duration</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Massachusetts</td>
<td>Temporary licenses were issued until mid-2020.</td>
<td>PHE terminates 6/15/2021.</td>
<td>Temporary licenses will soon be invalid.</td>
</tr>
<tr>
<td>Maine</td>
<td>Emergency license available to qualified out of state physicians.</td>
<td>PHE in place until at least 6/12/2021.</td>
<td>Emergency licenses remain effective.</td>
</tr>
<tr>
<td>Connecticut</td>
<td>Licensure requirement waived during CT PHE and 2 years thereafter.</td>
<td>License waiver in place until June 2023.</td>
<td>License waiver effective for (at least) two more years.</td>
</tr>
<tr>
<td>New York</td>
<td>License requirement waived through end of New York PHE.</td>
<td>NY PHE most recently extended through 6/24/21.</td>
<td>License waiver currently effective.</td>
</tr>
<tr>
<td>Florida</td>
<td>License requirement waived for up to 30 days of treatment for established patients during PHE.</td>
<td>PHE was most recently extended through 6/26/21.</td>
<td>License waiver currently effective for established patients.</td>
</tr>
</tbody>
</table>
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
What is a Value-Based Arrangement?

"Value-based participants" → "Value-based enterprise"

"Value-based arrangement" covers "value-based activities" to further "value-based purpose"

"Target patient population"
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
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
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)
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.