Hot Topics in Healthcare Compliance

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Introduction

Looking ahead: Regulatory and legislative developments in healthcare

• Industry changes, trends and the big picture
• Focus areas
  – Patient access to their data
  – Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)
• CMS final rules
  – Hospital Outpatient Prospective Payment System (OPPS)
  – Physician Fee Schedule (PFS)

Front of mind: Evolving areas of enforcement and focus

• Identifying areas of risk
  – OIG updates
  – Opioid epidemic
  – Population health
  – Privacy

Program effectiveness considerations

• Going beyond the seven elements
• Program maturity and stakeholder alignment

Looking ahead - Regulatory and legislative developments in healthcare
### Changes and trends in the healthcare industry

Paying for value, price transparency, and regulatory flexibility are key themes in the healthcare sector. Below are some topics where significant changes are either expected or already in progress.

<table>
<thead>
<tr>
<th>Medicare Advantage (MA)</th>
<th>The Quality Payment Program</th>
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<tbody>
<tr>
<td>• MA is a fast-growing area of the Medicare market share. Regulatory changes mean that plans may offer a wider range of services like transportation and groceries, while providers are no longer required to enroll in Medicare Part B to participate in an MA plan.</td>
<td>• In 2019, providers will begin to see penalties and rewards related to cost and quality measures under the Merit Incentive Payment System (MIPS). A variety of Advanced Alternative Payment Methods (AAPMs) encourage providers to take greater levels of outcomes-based risk and rewards.</td>
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<thead>
<tr>
<th>Medicare Part D</th>
<th>The Medicare Shared Savings Program</th>
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<tr>
<td>• Part D may take a greater role in negotiating Part B drug prices, while Part D plans have increased flexibility in plan design, including more limited formularies that may aid price negotiations with drug manufacturers.</td>
<td>• Accountable Care Organizations (ACOs) certified under Medicare will be expected to take on downside risk within two years, as opposed to the current six.</td>
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<tr>
<th>Prescription Drug Pricing</th>
<th>Changes to the Individual Health Insurance Market</th>
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<td>• The President’s Blueprint contains a number of policies to address the cost of prescription drugs. A new rule proposes to limit the use of rebates in drug prices, while other proposals increase the negotiating power of consumers and providers.</td>
<td>• The rollback of the Individual Mandate takes effect in 2019, while the introduction of short-term limited duration plans and association health plans will encourage many individuals covered in the Exchanges to seek coverage elsewhere.</td>
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<tr>
<th>Price Transparency</th>
<th>Promoting Interoperability</th>
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<td>• A proposed rule requiring drug manufacturers to include their standard list prices in direct-to-consumer advertising, and several requests for information on making price disclosure a condition of participation in Medicare have potential to increase competitive pressures across the health sector.</td>
<td>• The Administration is moving past requiring the use of health information technology to enabling health systems to share data without restriction, and Interoperability may become a Medicare condition of participation as well.</td>
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### Expanding patients’ access and control of their data

MyHealthEData seeks to give blue button access to all Medicare beneficiaries, and to create strong incentives for the private sector to follow suit.

- Medicare’s Blue Button 2.0 contains four years of Medicare Part A, B and D data for 53 million Medicare beneficiaries and provides multiple types of information including prescriptions and primary care treatments.
- The service will let Medicare beneficiaries give providers access to information on prescriptions and medical history.
- CMS has recruited over 100 new organizations to a developer preview program, which gives access to synthetic claims data so organizations may design applications to work with Blue Button 2.0.
- CMS is currently reviewing regulations and guidance for Medicare Advantage and Qualified Health Plans through the federally facilitated exchanges.
- CMS believes that the private plans that contract through Medicare Advantage and the exchanges should provide the same benefit that is being provided through Medicare’s Blue Button 2.0.

MACRA performance standards become more stringent

The MACRA statute and the Administration’s regulatory approach are coming together to demonstrate a rigorous implementation of the law, while retaining significant flexibilities.

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<tr>
<th>Performance Year</th>
<th>Performance Threshold</th>
<th>Additional Performance Threshold for Exceptional Performance</th>
<th>Payment Year</th>
<th>Statutory Payment Adjustment Range</th>
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<tr>
<td>2017</td>
<td>3 points</td>
<td>70 points</td>
<td>2019</td>
<td>+/- 4%</td>
</tr>
<tr>
<td>2018</td>
<td>15 points</td>
<td>70 points</td>
<td>2020</td>
<td>+/- 5%</td>
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<tr>
<td>2019</td>
<td>30 points</td>
<td>75 points</td>
<td>2021</td>
<td>+/- 7%</td>
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Under MIPS, CMS will weigh each performance category in 2019 as follows:

- Quality: 45%
- Cost: 15%
- Promoting Interoperability (PI; formerly Advancing Care Information): 25%
- Improvement Activities (IA): 15%

To qualify as AAPMs for payment year 2021 (2019 performance year) under the Medicare-only Option, clinicians in the 2019 performance period must:

- Receive at least 50% of Medicare Part B payments, or
- See at least 35% of Medicare Part B beneficiaries through a Medicare APM.

Clinicians can also qualify if they receive at least 50% of payments from all payers, or see at least 35% of patients, through a combination of Medicare AAPMs and Other Payer APMs.

CMS finalizes Medicare Hospital OPPS
Final rule published in the federal register on November 21, 2018

- **2019 OPPS rates**
  - Overall increase in OPPS rates for 2019 of 1.35 percent, up from 1.25 percent in the proposed rule
  - Rate increase factors in productivity adjustments and a 0.75 percent sequestration reduction

- **Non-excepted off-campus Provider-based Departments (PBDs)**
  - Bipartisan Budget Act (BBA) of 2015 included provisions aimed at eliminating the incentive for hospitals to acquire physician practices, convert the practices to PBDs, and receive higher Medicare payments.
  - Items and services furnished at off-campus PBDs are billed using Healthcare Common Procedure Coding System (HCPCS) codes and paid under OPPS.
  - Also, physician services at off-campus PBDs are eligible for payment under the Medicare Physician Fee Schedule (PFS) facility rate.
  - Off-campus PBDs that were not billing Medicare for covered services furnished prior to November 2, 2015, (the date of enactment for the law) generally are not eligible for payments under OPPS effective January 1, 2017.
  - Final rule expands certain policies that CMS adopted for 2017 as the agency implemented the BBA's site neutral payment provisions for the first time.


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CMS finalizes Medicare Hospital OPPS (continued)
Final rule published in the federal register on November 21, 2018

- **Clinic Visits**
  - Clinic visits to non-excepted off-campus PBDs (HCPCS code G0463) will be reimbursed at the PFS-equivalent rate.
  - To allay concerns of abrupt rate reduction, final rule provides a two-year phase-in of the PFS-equivalent rates:
    - 2019, 50 percent of the payment reduction will be applied for applicable clinic visit services, amounting to roughly 70 percent of the OPPS rate.
    - In 2020, the full reduction will occur, where clinic visits would be reimbursed at approximately 40 percent of the OPPS rate, as was initially proposed for 2019.
  - Medicare payments for a clinic visit to off-campus PBDs will be reduced from approximately $116 to $81 in 2019.

- **340B Drug Discount Policy (Evolving Issue)**
  - The final rule reduced payments for covered outpatient drugs under the 340B program from the standard rate of average sales price (ASP) plus 6 percent to ASP minus 22.5 percent for most hospital-affiliated providers.
  - However, a federal judge subsequently ruled that the HHS Secretary did not have the statutory authority to implement the 340B drug payment cuts.

CMS finalizes Medicare Hospital OPPS (continued)
Final rule published in the federal register on November 21, 2018

- **Hospital Outpatient Quality Reporting (OQR) program**
  - Hospitals are required to report on quality measures for services rendered in an outpatient hospital setting to avoid a 2 percent decrease in OPPS rates
  - To reduce administrative burden and focus on more meaningful quality measures, CMS proposes to remove eight measures from OQR reporting requirements in 2019, one in 2020, and seven more in 2021

Medicare PFS final rule
Final rule issued November 1, 2018

- **Physician payment rates**
  - Physician fee schedule conversion factor is $36.04, which is up from $35.99 this year

- **E/M coding and payment changes**
  - Final rule will allow providers to use 1995 or 1997 Evaluation & Management (E/M) documentation guidelines and current coding and payment structure for E/M codes will continue in CY2019 and CY2020
  - In 2021 and beyond, CMS will consolidate payment rates for E/M visit levels 2 through 4 while maintaining payment rate for E/M level 5
  - The final rule also alleviates provider burden by introducing the following policies:
    - Elimination of the requirement to document the medical necessity of a home visit instead of an office visit
    - For established patient office visits, when relevant information is already contained in the medical record, practitioners may choose to focus their documentation on what has changed since the last visit, or on pertinent items that have not changed.
    - Removal of potentially duplicative requirements for notations in medical records that may have previously been included in the medical records by residents or other members of the medical team for E/M visits furnished by teaching physicians.
    - Practitioners are allowed to review and verify certain information in a patient's medical record that is entered by ancillary staff or the patient, rather than re-entering the information


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E/M payment amounts now and in 2021

E/M coding allows Medicare billers to translate the patient visit experience into the information needed by Medicare to appropriately reimburse for those visits. E/M codes distinguish visits based on the level of complexity, site of service, and whether the patient is new or established. The 2019 PFS Final Rule pushed back implementation of a collapsing of E/M coding categories and allowed for more add-on payments to account for particular circumstances.

<table>
<thead>
<tr>
<th>Complexity Level under CPT</th>
<th>Current (2018) Payment Amount</th>
<th>Revised Payment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Visit Code Alone</td>
<td>Visit Code with Either Primary or Specialized care add-on code</td>
</tr>
<tr>
<td>New Patient</td>
<td></td>
<td></td>
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<tr>
<td>Level 2</td>
<td>$76</td>
<td>$130</td>
</tr>
<tr>
<td>Level 3</td>
<td>$110</td>
<td>$187</td>
</tr>
<tr>
<td>Level 4</td>
<td>$211</td>
<td>$211</td>
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<tr>
<td>Established Patient</td>
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<tr>
<td>Level 2</td>
<td>$45</td>
<td>$90</td>
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<tr>
<td>Level 3</td>
<td>$77</td>
<td>$77</td>
</tr>
<tr>
<td>Level 4</td>
<td>$100</td>
<td>$100</td>
</tr>
<tr>
<td>Level 5</td>
<td>$148</td>
<td>$148</td>
</tr>
</tbody>
</table>


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Medicare PFS final rule (continued)
Final rule issued November 1, 2018

• Telehealth services:
  – CMS will pay physicians when they check in with Medicare beneficiaries through telephone or other telecommunications device (HCPCS code G2012)
  – Physicians to also be paid for time spent to review video or image sent by a patient to assess if a visit is required (HCPCS code G2010)
  – CMS is also finalizing policies to pay separately for new coding describing chronic care remote physiologic monitoring (CPT codes 99453, 99454, and 99457) and interprofessional internet consultation (CPT codes 99451, 99452, 99446, 99447, 99448, and 99449). The proposed date for finalizing is January 1, 2019.

• Merit-based Incentive Payment System (MIPS)
  – CMS is adding eight new measures in 2018 which includes four based on patient reported outcomes
  – 26 quality measures have been removed
  – CMS is expanding MIPS program to include non-physician providers such as physical therapists, occupational therapists, speech pathologists, audiologists, clinical psychologists, and registered dietitians or nutrition professionals
  – Clinicians who may have been excluded previously from MIPS due to low-volume threshold will now have an option to participate

Regulatory landscape

Growing Audit Synergies

Medicare Part B

Extrapolation?
Facility Denial
Mapping to Professional Services?

Medicare Part A

RACs & ZPICs

CMS MAC*

Data sharing between contractors

Other State Agencies

• Medicaid
  Integrity Contractors (MICs)
• Medicaid Fraud
  Control Units

Federal Agencies

• Health Resources & Services
  Administration (HRSA)
• Office of Civil Rights (OCR)
• Health Care Fraud
  Prevention task force
• Federal Bureau of
  Investigation (FBI)
• Office of Inspector General
  (OIG)
• Department of Justice (DOJ)

Department of Health & Human Services

*Medicare Administrative Contractor

OIG FY 2018 year in review

1. 764 criminal actions
2. 813 civil actions
3. $2.91B+ in expected recoveries
4. Exclusion of 2,712 individuals & entities

Where should you look to identify risks?

Select OIG active work plan items
- Hospitals’ Compliance with Medicare’s Transfer Policy With the Resumption of Home Health Services and the Use of Condition Codes
- Physicians Billing for Critical Care Evaluation and Management Services
- Review of Post-Operative

Select areas of interest from OIG hospital compliance reviews
- Medicare criteria for acute inpatient rehabilitation facilities
- Patient discharge status codes and transfers to home health services
- Adjusted claims for replaced medical devices
- Payments for behavioral health services

*The Health Insurance Portability and Accountability Act of 1996

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Developing the compliance risk universe
Identifying relevant enterprise-wide compliance risks

Key compliance risk sources:
- Internal sources of regulatory information (e.g., policies, reports, contract requirements, etc.)
- External sources of regulatory information (e.g., OIG guidance, workplans, and activity, new regulations, OCR activity, etc.)
- Organization’s institutional knowledge
- Industry scan

Compliance Risk Universe – Illustrative Only

Some questions to consider when developing the compliance risk universe:
- What regulatory compliance risk areas are applicable to this organization?
- What sources (both internal and external) should be included, given applicable compliance risk areas, for a comprehensive compliance risk universe?
- Where across the organization do key compliance risks reside (e.g., revenue cycle, information technology, operations, clinical, etc.)?
Opioid epidemic

Curbing the opioid epidemic – OIG highlights

Key statistics (from January 2018 OIG testimony)
- More than 50,000 Americans died from drug overdoses in 2015, of which 63% reportedly involved opioids.
- According to the Centers for Disease Control and Prevention (CDC), approximately 3 out of 4 new heroin users report having abused prescription opioids prior to using heroin.
- Prescription drug diversion is a serious component of this epidemic.

Key takeaways from OIG’s opioid fraud enforcement efforts
- From July 2018 OIG report, Opioid Use in Medicare Part D Remains Concerning:
  - Nearly one in three Part D beneficiaries received a prescription opioid in 2017.
  - Overall Part D spending for opioids decreased, due in part to declining prices.
  - Almost 460,000 beneficiaries received high amounts of opioids in 2017, fewer than in 2016.
  - About 71,000 beneficiaries are at serious risk of opioid misuse or overdose, also fewer than in 2016.
  - Almost 300 prescribers had questionable opioid prescribing for the 71,000 beneficiaries at serious risk.
  - The high level of opioid use continues to call for the public and private sectors to work together to address this crisis.

Curbing the opioid epidemic
Federal takedown of improperly prescribing clinicians

- The largest ever federal takedown included opioid related charges against 600 individuals; defendants included 76 physicians charged for their roles in prescribing and distributing opioids.
- Between July 2017 and June 2018, OIG issued exclusion notices to 587 individuals based on their conduct related to opioid diversion and abuse.
- OIG analyzed Medicare Part D data to identify opioid prescribing patterns, highlighting 15,000 beneficiaries appeared to be “doctor shopping.”
- In Ohio, OIG completed the first state-specific Medicaid review focused on curbing the opioid epidemic and found more than 700 beneficiaries in Ohio at risk of prescription opioid misuse; nearly 50 prescribers stood out by ordering opioids for more of these beneficiaries than other prescribers.

Population health compliance considerations
Population health compliance
Expanding boundaries, increasing complexity, and rising revenue associated with population health are forcing health care provider organizations to evaluate their foundational capabilities to manage compliance risk now and in the future.

Population health compliance – common challenges among programs
Can you support your clinicians with the requisite data collection, validation, reporting and monitoring needs associated with Payment Program eligibility, performance, and compliance? The strength of your capabilities and competencies related to the clinical, operational, and electronic health record-workflow design and effectiveness can contribute greatly to your success.
Privacy and security of patient information continues to be an area of expanding focus and enforcement. Existing challenges are met with new emerging risks in today’s growing health data world.

- Compliance Risks and Vulnerabilities
  - Health apps and consumer health devices
  - Data leakage and breaches
  - Insider threats
  - Lack of auditing and monitoring
  - Cyberattacks
  - Business associates
  - Device access and encryption
  - Growing prevalence of telemedicine

In 2018, the OCR’s largest HIPAA settlement included fines in excess of $15 million.
Program effectiveness considerations

HCCA-OIG resource for compliance program effectiveness
Operational and effective compliance programs should go much deeper than evaluating general risk areas

Elements of an effective compliance program

- Investigations and remedial measures
- Standard policies and procedures
- Compliance program administration
- Screening and evaluation of employees, vendors, physicians, and agents
- Communication, education, and training on compliance issues
- Monitoring, auditing, and internal reporting systems

Corrective action

- Ownership of corrective action (administrative vs. compliance)
- Determine if corrective action(s) address root cause
- Monitor corrective action progress
- Document corrective action(s)
- Evaluate effectiveness of corrective actions on addressing root cause

Root cause

- Investigate issues to identify root cause
- Identify contributing factors
- Determine root cause of identified issue
- Maintain documentation that illustrates the root cause(s)
- Catalog and track root cause activity

Behaviors drive effective compliance programs
More emphasis on behavior and less on checklists

THEN
Focus on metrics
• Trainings
• Calls/hotlines
• Studies
• Tools/Checklist

NOW
Focus on behaviors
• Ethical decision-making
• Organizational justice
• Freedom of expression

Source: Ethics and Compliance Program Effectiveness Report, 2016, LRN,
https://cdn2.hubspot.net/hubfs/319387/PEI%20Report%202016_interactive_2.6.pdf?ct=1488382377944

Considering program maturity
Going beyond effectiveness to consider leading practices

<table>
<thead>
<tr>
<th>DOJ Evaluation Topics</th>
<th>Unstructured/Reactive</th>
<th>Evolving</th>
<th>Proactive/Optimized</th>
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<tr>
<td>Analysis and Remediation of Underlying Misconduct</td>
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<td>Senior and Middle Management</td>
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<td>Autonomy and Resources</td>
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<td>Policies and Procedures</td>
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<td>Training and Communications</td>
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<td>Confidential Reporting and Investigation</td>
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<td>Incentives and Disciplinary Measures</td>
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<td>Continuous Improvement, Periodic Testing and Review</td>
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<td>Mergers and Acquisitions (M&amp;A)</td>
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Considering program stakeholders beyond compliance
Creating alignment to meet program objectives

- Are the roles and responsibilities clearly defined?
- Do they encompass all of the guidance’s suggestions?
- Are there any overlapping roles and/or responsibilities?
- Are there any areas of duplication of efforts?

- Are the programs independent in both fact and appearance?
- Does the compliance officer and counterparty have separate reporting opportunities with the management board & with the Board/Boarders & Committee?
- Do the charters of the Compliance and Legal functions address this independence?
- Does the board evaluate the independence of the different functions on a periodic basis?

Operationalization of the Compliance Function

- How are Compliance, Legal, Human Resources, and Tax collaborate?
- Do the charters of each program collaboration?
- Are topics like the structure, reporting relationships, and interaction of Corporate Responsibility, Legal, Human Resources, and Tax and included as departmental roles and responsibilities?

Information and Communication
- How is appropriate access to information needed by conduct compliance activities ensured?
- Are the charters of the Compliance and related functions ensure appropriate access to information?
- What common frameworks and definitions are used to enable decisions regarding the resolutions of compliance issues?

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