# Hot Topics in Healthcare Compliance

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## Hot Topics in Healthcare Compliance


Lee Decker
*VP & Chief Compliance Officer*
**Novant Health, Inc.**

Heather Hagan
*Advisory Senior Manager*
**Deloitte & Touche LLP**

## Agenda

**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.

**Medicare Advantage (MA)**

- 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.

**The Quality Payment Program**

- 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.

**Medicare Part D**

- 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.

**The Medicare Shared Savings Program**

- Accountable Care Organizations (ACOs) certified under Medicare will be expected to take on downside risk within two years, as opposed to the current six.

**Prescription Drug Pricing**

- 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.

**Changes to the Individual Health Insurance Market**

- 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.

**Price Transparency**

- 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.

**Promoting Interoperability**

- The Administration is moving past requiring the use of health information technology to enabling health systems to share data without restriction, and that consumers have full control over their medical information. Interoperability may become a Medicare condition of participation as well.




## 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.

Source: Trump Administration Announces MyHealthEData Initiative at HIMSS18. CMS Press Release, March 6, 2018.

## 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.

| Performance Year | Performance Threshold | Additional Performance Threshold for Exceptional Performance | Payment Year | Statutory Payment Adjustment Range |
|---|---|---|---|---|
| **2017** | 3 points | 70 points | 2019 | +/- 4% |
| **2018** | 15 points | 70 points | 2020 | +/- 5% |
| **2019** | 30 points | 75 points | 2021 | +/- 7% |

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 AAPM.

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.

Source: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019. Accessible at: https://www.federalregister.gov/documents/2018/11/23/2018-24170/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions




# CMS finalizes Medicare Hospital Outpatient Prospective Payment System (OPPS)

## 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.

Source: https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center




## 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.

Sources: https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center
https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-25

## 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

Source: https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center




# CMS final rule for updates to payment policies, rates and quality provisions for services furnished under Medicare Physician Fee Schedule (PFS)

## 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

Source: https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year





## 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.

| | | **Current (2018) Payment Amount** | **Revised Payment Amount** | | | | |
|---|---|---|---|---|---|---|---|
| | Complexity Level under CPT | Visit Code Alone | Visit Code Alone Payment | Visit Code with Either Primary or specialized care add-on code | Visit Code with New Extended Services Code (Minutes Required to Bill) | Visit with Both Add-on and Extended Services Code Added | Current Prolonged Code Added (Minutes Required to Bill) |
| **New Patient** | Level 2 | $76 | $130 | $143 | $197 (at 38 minutes) | $210 | n/a |
| | Level 3 | $110 | | | | | |
| | Level 4 | $167 | | | | | |
| | Level 5 | $211 | $211 | n/a | n/a | n/a | $344 (at 90 minutes) |
| | | | | | | | |
| **Established Patient** | Level 2 | $45 | $90 | $103 | $157 (at 34 minutes) | $170 | n/a |
| | Level 3 | $74 | | | | | |
| | Level 4 | $109 | | | | | |
| | Level 5 | $148 | $148 | n/a | n/a | n/a | $281 (at 70 minutes) |

Source: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019. Accessible at: https://www.federalregister.gov/documents/2018/11/23/2018-24170/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions

## Medicare PFS final rule (continued)

Final rule issued November 1, 2018

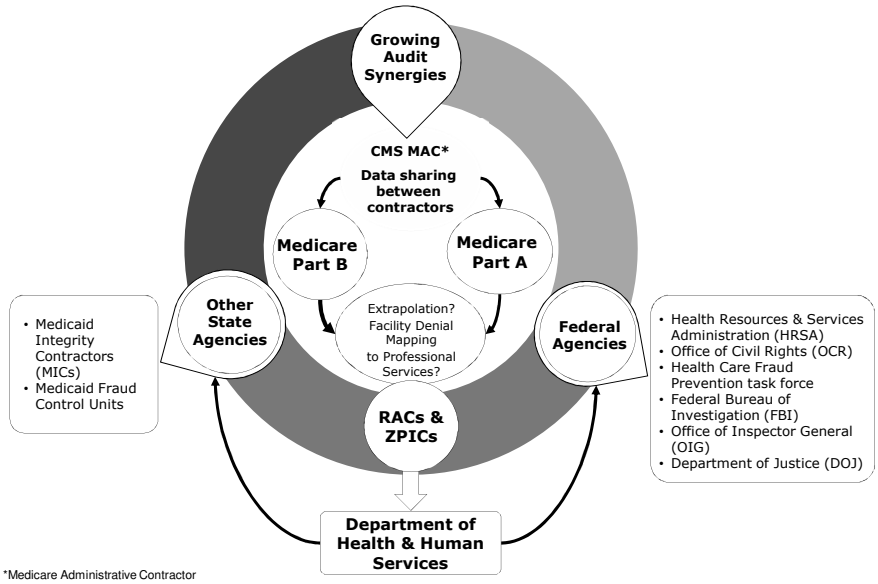
- **Telehealth services:**
  - CMS will pay physicians when they check in with Medicare beneficiaries through telephone or other telecommunications device (HCPCS code G2012)
  - Physicians to also be paid for time spent to review video or image sent by a patient to assess if a visit is required (HCPCS 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

Source: https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year




# Front of mind: Evolving areas of enforcement and focus

## Regulatory landscape

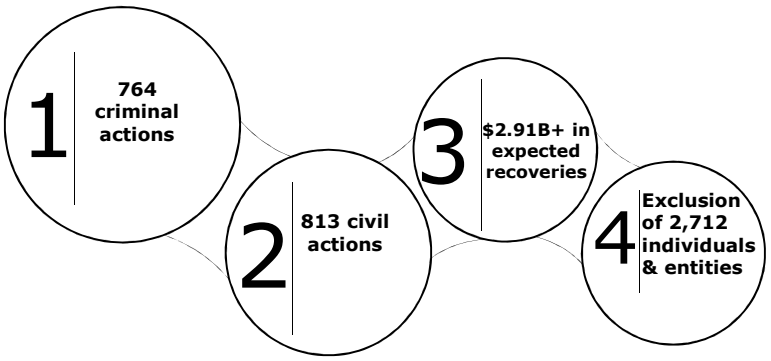



*Medicare Administrative Contractor



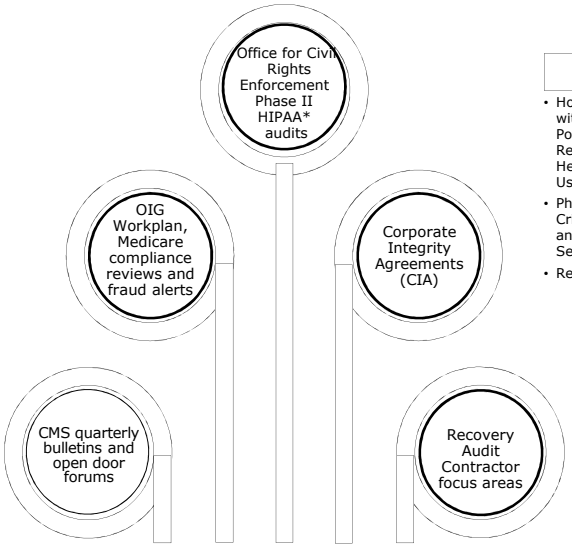


## OIG FY 2018 year in review




Source: https://oig.hhs.gov/reports-and-publications/archives/semiannual/2018/2018-fall-sar.pdf

## 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 Services Provided in the Global Surgery Period
- Review of Home Health Claims for Services With 5 to 10 Skilled Visits
- Medicare Part B Payments for End-Stage Renal Disease Dialysis Services

**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





## 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

| | | | |
|---|---|---|---|
| **1. Culture / Governance**<br>✓Culture / Tone at the Top<br>✓Policies and Procedures<br>✓Roles and Responsibilities<br>✓Compliance Function<br>✓Board Structure and Education | **2. Institutional Compliance Program**<br>✓Code of Conduct<br>✓Training and Education<br>✓Communication<br>✓Disciplinary Action<br>✓Policies and Procedures<br>✓Auditing and Monitoring<br>✓Response and Prevention | **3. Departmental Compliance Program**<br>✓ED<br>✓Wound Care<br>✓Cancer<br>✓Lab<br>✓Radiology<br>✓Operational Departments and Compliance | **4. Contract Management**<br>✓Physician Arrangements<br>✓Joint Ventures<br>✓Vendor Agreements<br>✓Contract Repository |
| **5. Conflict of Interest**<br>✓Board level<br>✓Executive leadership and management<br>✓Non-employed Physicians | **6. Clinical Research**<br>✓Research Compliance Program<br>✓Clinical Trials Billing<br>✓Human Subject Protection<br>✓Scientific Misconduct<br>✓Grant Management | **7. Quality / Performance Improvement**<br>✓Patient Safety<br>✓Medical Errors<br>✓Quality Indicator Monitoring and Reporting<br>✓Joint Commission Review | **8. Hospital Coding and Billing**<br>✓Charge Master (CDM)<br>✓Charge Capture<br>✓Monitoring and Auditing<br>✓Care Coordination<br>✓Training and Education |
| **9. Professional Coding and Billing**<br>✓Training and Education<br>✓Physician Documentation and Coding<br>✓Auditing and Monitoring | **10. Privacy and Security**<br>✓Access and Permissions<br>✓Physical Security<br>✓Privacy, Security, and Compliance | **11. Materials Management / Procurement**<br>✓Materials Management Compliance Program<br>✓Purchasing<br>✓Purchase Cards<br>✓Accounts Payable | **12. Specific Compliance/ Regulatory Risks**<br>✓Government Audit Readiness<br>✓Provider-Based Status<br>✓Durable Medical Equipment<br>✓EMTALA<br>✓Cost reporting issues/opportunities |

**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.

Sources: https://oig.hhs.gov/testimony/docs/2018/cantrell-testimony-01172018.pdf , https://oig.hhs.gov/oei/reports/oei-02-18-00220.pdf

## 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

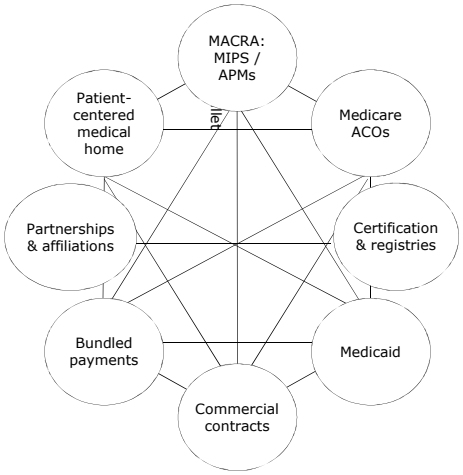



Source: https://oig.hhs.gov/reports-and-publications/archives/semiannual/2018/2018-fall-sar.pdf

# 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

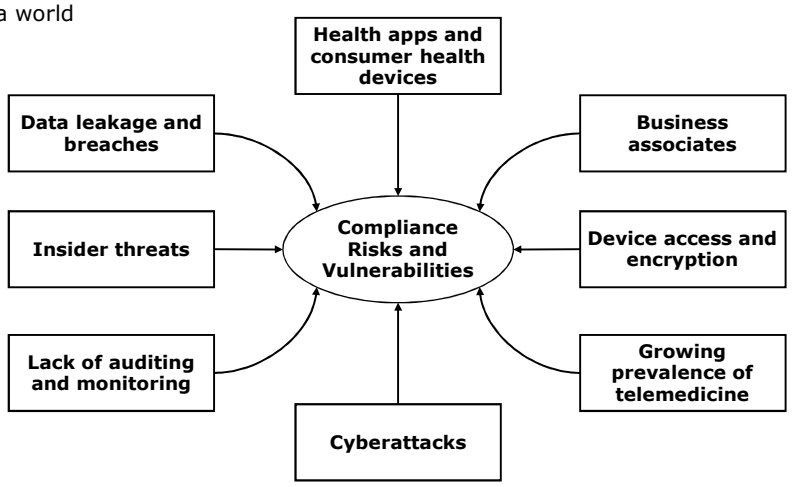
Can you ***support your clinicians with the requisite data collection, validation, reporting and monitoring needs*** associated with Payment Program eligibility, performance, and compliance? The strength of your capabilities and competencies related to the clinical, operational, and electronic health record–workflow design and effectiveness can contribute greatly to your success.

# Information privacy




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




2018 saw the OCR's largest HIPAA settlement with 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


Source: https://oig.hhs.gov/compliance/compliance-resource-portal/files/HCCA-OIG-Resource-Guide.pdf

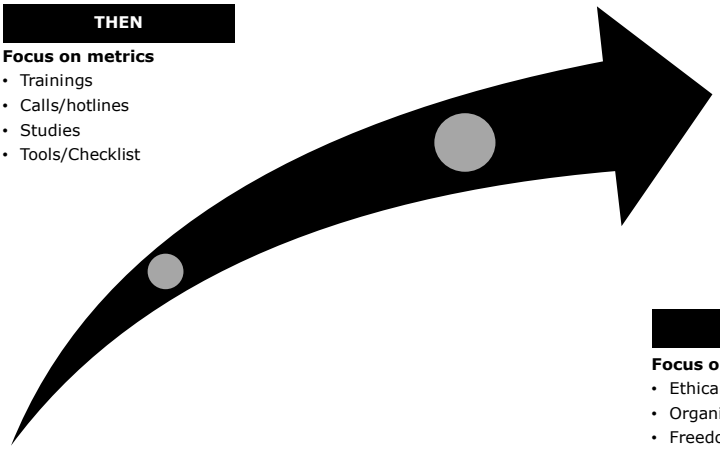
## Behaviors drive effective compliance programs

More emphasis on behavior and less on checklists

**THEN**

**Focus on metrics**

- Trainings
- Calls/hotlines
- Studies
- Tools/Checklist



**Effective compliance program**

**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?t=1488382370944





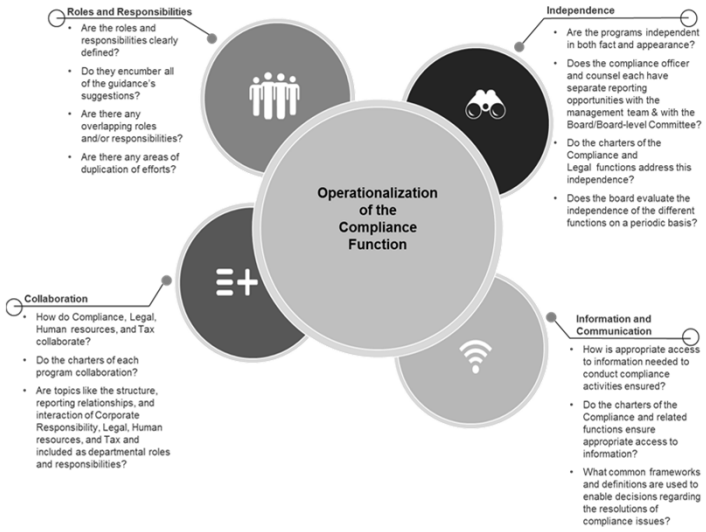
## Considering program maturity

Going beyond effectiveness to consider leading practices

| DOJ Evaluation Topics | Unstructured/ Reactive | Evolving | Proactive/ Optimized |
|---|---|---|---|
| Analysis and Remediation of Underlying Misconduct | | | ◇ |
| Senior and Middle Management | | | ◇ |
| Autonomy and Resources | | ◇ | |
| Policies and Procedures | | ◇ | |
| Risk Assessment | | | ◇ |
| Training and Communications | | ◇ | |
| Confidential Reporting and Investigation | | ◇ | |
| Incentives and Disciplinary Measures | | ◇ | |
| Continuous Improvement, Periodic Testing and Review | ◇ | | |
| Third Party Management | | | ◇ |
| Mergers and Acquisitions (M&A) | | ◇ | |

## Considering program stakeholders beyond compliance

Creating alignment to meet program objectives





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