Deloitte.

NEHIA 2022 Annual Conference

November 30, 2022

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Discussion Topics

Compliance Program Effectiveness, with Spotlight on Data Analytics and Risk Assessment

Risk and Audit Considerations – Current Hot Topics, Including Enforcement Focus and Pandemic Impacts

Forward Looking Regulatory Landscape – Things We're Keeping an Eye On

Compliance Program Effectiveness

Compliance Program Effectiveness | Key takeaways from the DOJ

The most recent (June 2020) updates to the DOJ guidance addressed a number of topics which align with leading practices we sometimes observe and often recommend.

Key updates for compliance leaders

- Overarching Takeaways
    - Emphasis and focus on the **structure, evaluation, adequate resourcing and empowerment** of the Compliance Program, as well as continuous risk assessment and access to data, policy and training effectiveness, third-party risk management and post-M&A integration.
- Program Design
    - **Evolving the continuous risk assessment**, including the structure and evolution of the compliance program, continuous access to enterprise data to assess risk and incorporating lessons learned into risk assessments
    - **Enhanced effectiveness measures for core program functions**, including tracking employee attention and attraction to policies, shorter, targeted training offerings, evaluating training impact and hotline effectiveness
    - **Deeper involvement with third-party risk and M&A**, including an understanding of third-party risks throughout the relationship (not just onboarding), as well as pre- and post-acquisition integration and diligence efforts
- Program Resourcing and Empowerment
    - Commitment and implementation of a **culture of compliance at all levels** of the organization, including middle and top
    - Ensuring those with day-to-day operational responsibility have **adequate resources, appropriate authority and direct access** to governing authority
    - Enabling compliance function effectiveness through **investment in training and development and access to relevant data sources**
- Program "Working in Practice"
    - Continuing to **evolve based on lessons learned** – both internal lessons and from similar organization

Source: https://www.justice.gov/criminal-fraud/page/file/937501/download

Fundamental Questions

The following questions are instrumental in determining program effectiveness:

1

Is the corporation's compliance program well designed?

- Adequately designed compliance programs should be effective in preventing and detecting misconduct and wrong doing by employees
- Well-designed compliance programs should be updated periodically through additional risk assessments

2

Is the program being applied earnestly and in good faith? In other words, is the program being implemented effectively?

- Management should demonstrate a commitment to the compliance program

3

Does the corporations compliance program work in practice?

- Effective compliance programs need to work in practice not just on paper
- Prosecutors will evaluate if programs were working when misconduct was identified

Source: https://www.justice.gov/criminal-fraud/page/file/937501/download

Program Design

According to the DOJ, risk assessments, policies and procedures developed by appropriate parties, tailored trainings and communications, and third party and M&A due diligence are essential in creating a well-designed compliance program.

Risk Assessment

Companies should identify, assess, and define its risk profile and the degree to which the program devotes appropriate scrutiny and resources to a spectrum of risks.

Areas evaluated:
- Risk Management Process
- Risk-Tailored Resource Allocation
- Updates and Revisions

Policies and Procedures (P&Ps)

P&Ps should aim to reduce risks identified from the risk assessment. Codes of conduct should detail commitment to comply with federal laws.

Areas evaluated:
- Design
- Comprehensiveness
- Accessibility
- Responsibility for Operational Integration
- Gatekeepers

Trainings and Communications

Trainings, certifications, and communications should be tailored and conducted periodically to ensure integration within the company.

Areas evaluated:
- Risk-based Training
- Form/Content/Effectiveness of Training
- Communications about Misconduct
- Availability of Guidance

Confidential Reporting & Investigation Process

Companies should have an efficient and trusted mechanism to confidentially report misconduct.

Areas evaluated:
- Effectiveness of the reporting mechanism
- Properly scoped investigations by qualified personnel
- Investigation response
- Resources and tracking of results

Third Party Management

Companies should apply risk-based due diligence to it's third party relationships.

Areas evaluated:
- Risk-based and integrated processes
- Appropriate controls
- Management relationships
- Real actions and consequences

Merger and Acquisitions (M&A)

Compliance programs should include comprehensive due diligence of acquisition targets.

Areas evaluated:
- Due diligence process
- Integration in the M&A process
- Process connecting due diligence to implementation

Source: https://www.justice.gov/criminal-fraud/page/file/937501/download

Program Implementation

Management's commitment to the compliance program is arguably one of the most important factors the government examines to assess effectiveness.

Commitment by Senior and Middle Management

- **Company leaders set the tone for a culture of compliance**
  - Prosecutors will evaluate how senior management has articulated the company's ethical standards, and how middle management has encouraged employees to abide by the standards.

Autonomy and Resources

- **Day to day oversight is essential for the effective implementation of compliance programs**
  - Prosecutors will evaluate if those in charge of compliance program oversight act with adequate authority, have sufficient seniority within the organization, receive sufficient resources and staff, and possess sufficient autonomy from management

Incentives and Disciplinary Measures

- **Compliance programs should have established incentives for compliance and disincentives for non-compliance**
  - Prosecutors will assess if the company has clear disciplinary procedures established, enforces the disciplinary procedures consistency across the organization, and ensures that procedures correspond with the violations

Source: https://www.justice.gov/criminal-fraud/page/file/937501/download

Program in Practice

When misconduct occurs, prosecutors will review how the company detected the potential misconduct, what resources were in place to investigate, and the thoroughness and effectiveness of the company's remediation efforts.

Continuous Improvement, Periodic Testing and Review

Compliance programs should have the capacity to improve and evolve. Internal audit should conduct periodic compliance audits, and the company should also test compliance controls and perform gap assessments.

Investigation of Misconduct

Compliance programs should have a funded mechanism for the timely and thorough investigation of any allegation of misconduct by the company, its employees, or agents.

Analysis and Remediation of Any Underlying Conduct

Compliance programs should enable companies to conduct thoughtful root cause analysis of misconduct and timely and appropriate remediation of the root causes.

Source: https://www.justice.gov/criminal-fraud/page/file/937501/download

Effectiveness: Spotlight on Data Analytics

The Department of Health and Human Services (HHS) and the Department of Justice (DOJ) encourage compliance officers to use data as an essential tool to fight fraud in their organizations.

What officials are saying

"**Data has allowed us to fight fire with fire**… We have made a tremendous investment in data capability. We have to keep pace with what the fraudsters are doing."

- Christi Grimm, HHS Inspector General

"**You need to have a seat at the table** and access to the data your organization has… **The siloed walls need to be broken down** and your company's leadership needs to understand"

- Kenneth Polite, DOJ Assistant Attorney General, Criminal Division

"If you do have an occasion to advocate to the Department of Justice and there are questions about your compliance program, the question will be for the compliance officer. **Make sure they are equipped to answer those questions**.."

- Kenneth Polite, DOJ Assistant Attorney General, Criminal Division

What compliance officers can do to get ahead

Identify the most important touchpoints in the organization, and develop compliance resources to match those risk profiles

Officials from the OIG and DOJ recommend using your organization's data to understand where compliance needs to lean in more and where to invest further in data capabilities.

Understand how the technology has aided fraud in going national

Technology has allowed fraud to be committed at a larger scale. To adapt to the changing landscape, the OIG plans to add digital investigators, forensic, auditors, and cybersecurity professionals to teams.

Do what you can to identify fraud on the local level

While the federal government is responsible for investigating fraud, Grimm and Polite encourage compliance officers to use data analysis to identify the biggest risks and train resources to respond, noting investigating and prosecuting health care fraud is a "community effort."

Source: Report on Medicare Compliance Volume 31, Number 37, October 10, 2022.

Department of Justice (DOJ) guidance—data can support effective operations

DATA RESOURCES & ACCESS[1]

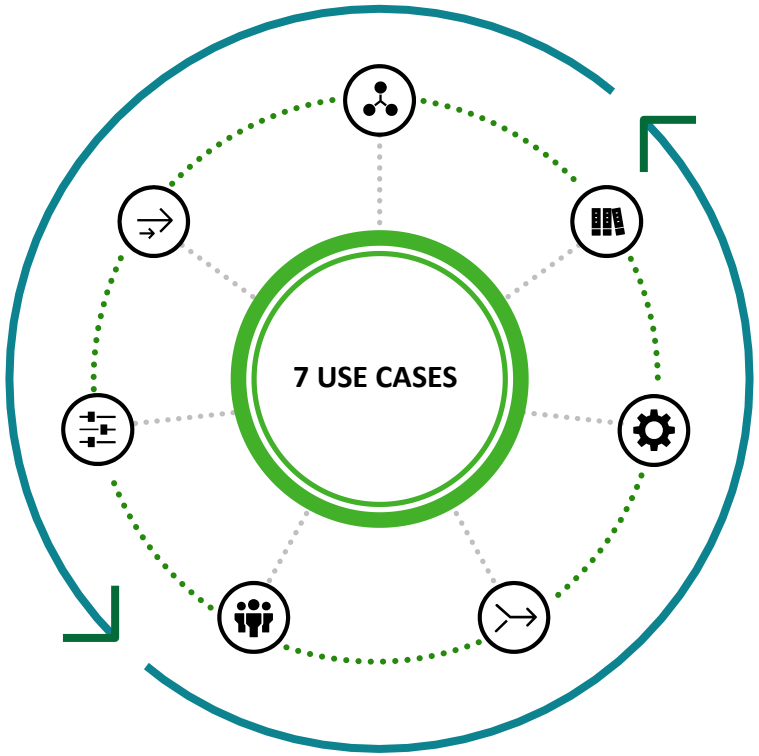
1. **Do compliance and control personnel have sufficient direct or indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing of policies, controls, and transactions?**
2. **Do impediments exist that limit access to relevant sources of data and, if so, what is the company doing to address the impediments?**

DOJ FOCUS AREAS	IMPLICATIONS	EXAMPLE DATA ANALYTICS PRACTICES
Risk assessment	Identify, analyze, and address key organizational risks	• Connect tools to operational data and information across functions so that controls are tested on an ongoing basis and not just a "point in time" • Build a library of potential risks and lessons learned from prior risk assessment
Policies and procedures	Describe ethical norms, address, and aim to reduce risks identified by the company as part of its risk assessment process	• Track employees' access to various policies and procedures to help the organization gain a better understanding of what trends exist of policies and procedures that generate the most searches and attention
Autonomy and resources	Requisite authority and stature for those charged with a compliance program's day to-day oversight	• Compliance and control personnel need access to relevant sources of data to allow for the timely and effective continuous monitoring and/or testing of policies and controls and transactions
Incentives and disciplinary measures	Incentives for compliance and disciplinary action for non-compliance	• Ability to monitor and track investigations over a period of time and resulting discipline to assist with consistency across an organization
Continuous improvement, periodic testing, and review	An effective compliance program implements controls that will reveal areas of risk for improvement to the program	• An organization can focus on using data analytics to support effective operations by adapting its compliance program based upon prior year findings for areas that lack efficiency or are deemed not effective
Analysis and remediation of underlying misconduct	Conduct a thoughtful root cause analysis of misconduct and timely and appropriately remediate to address the root causes	• An organization can use data analytics to identify prior indications of misconduct and evaluate different trends observed from continuous data monitoring

1. US Department of Justice Criminal Division, Evaluation of Corporate Compliance Programs (Update June 2020) https://www.justice.gov/criminal-fraud/page/file/937501/download.

Examples of data analytics

Following are examples of using data analysis for strategic actionable goals:



Professional coding	• Benchmarking physician Current Procedural Terminology (CPT) usage for appropriateness, risk-based reviews, and identification of outliers for investigation and resolution • Benchmarking is done using commercially available as well as CMS Provider Utilization & Payment Data Public Use File, and Individual Medicare Administrative Contractor (MAC) reports
Hospital revenue	• Analyzing inpatient and outpatient paid claims data and reviewing medical record documentation to inform impact on payments/accounts, comparison of average length of stay to geometric mean length of stay • Analyzing potential lost revenue through denials and Program for Evaluating Payment Patterns Electronic Report (PEPPER) data to identify high dollar, potential high-risk coding, and short-stay claims for further analysis
Drug unit billing	• Analyzing drug units and spending per unit to identify operational improvement and savings opportunities due to a reduction in drug waste and drug spending
Clinical documentation improvement	• Performing clinical documentation and reimbursement analysis for inpatient Medicare, Medicaid, and commercial plans to identify areas of potential revenue, compliance, and quality risk areas and/or opportunities • Medical Provider and Analysis Review (MEDPAR) data and specific Medicaid databases are utilized to perform analysis on claims submitted to governmental payors while Truvan data is utilized for commercial payors
Quality data	• Benchmarking quality data against national averages to identify potential areas for coding and documentation improvement, and focus areas for improvement of quality and safety indicator scores that may be related to provider documentation and code assignments • Hospital Compare, Healthgrades, and Leapfrog are used as sources for benchmark data
Telehealth reimbursement	• Analyzing billed, submitted, and paid claims data for status and/or questionable billing patterns for services
Payment aberrations	• Analyzing payments received from payors, bills submitted to payors, to determine whether appropriate reimbursement is received for services rendered

Effectiveness: Spotlight on Risk-Based Billing Compliance

Billing Compliance Risk Assessment Inputs

INTERNAL INPUTS

- ✓ Data Mining
- ✓ Prior Audits (Internal & External Issues)
- ✓ Reported Internal Concerns
- ✓ Discussion with Management

EXTERNAL INPUTS

- ✓ Comparative Billing Reports
- ✓ OIG Workplan
- ✓ Medicare TPE Reviews

Industry Hot Topics for Hospital Billing Compliance Risk Areas

Service Area	Risk Areas
Inpatient Services	▪ Inpatient Rehabilitation ▪ Admissions with a payment greater than charges ▪ Short stays ▪ Outlier payments ▪ Outlier DRGs ▪ Claims billed with 1 CC or MCC ▪ Inpatient Behavioral Health (IPF) documentation and medical necessity ▪ Total Joint Replacements
Outpatient Services	▪ Outpatient outlier payments ▪ Medical Device Credits ▪ Hospice Services ▪ Physical/Occupational/Speech Therapy ▪ Facet Joint Injections ▪ Level 5 Emergency Department Services ▪ Pulmonary Rehabilitation Services ▪ Appropriate Use (Radiology)

Industry Hot Topics for Professional Billing Compliance Risk Areas

Service Area	Risk Areas
Professional Services	▪ Telemedicine/Remote Patient Monitoring ▪ Behavioral Health ▪ Routine Foot Care ▪ Modifier 25 ▪ Pain Management ▪ Ophthalmology (cataract surgery, injections) ▪ HRSA claims ▪ Critical Care ▪ Split-Shared Visits ▪ Chronic Care Management

Risk and Audit Considerations – Current Hot Topics

OIG and DOJ Enforcement

Current Hot Topics

HHS-OIG's Semiannual Report: Overview

Setting the stage: Health and Human Services (HHS) OIG's Semiannual Report describes OIG's work identifying significant risks, problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations

The table below highlights significant results (across four semiannual periods) of selected audits, evaluations, and enforcement activities

57% decrease in new audit and evaluation recommendations from the Oct 2020 – Mar 2021 reporting period

45% increase in criminal actions from the Oct 2020 – March 2021 reporting period

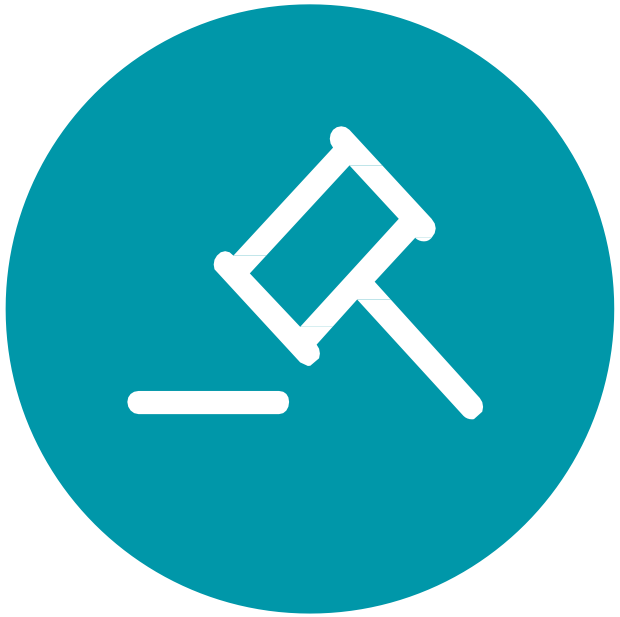
	Reporting Period			
Statistic	***Oct '21- March '22***	***Apr '21- Sept '21***	***Oct '20- March '21***	***Apr '20- Sept '20***
Audit Report Issued	47	162	75	178
Evaluations	14	46	20	44
Expected Audit Recoveries	$1.14 billion	$787.29 million	$566.46 million	$942.06 million
Questioned Costs	$1.6 billion	$1.17 billion	-	$733.93 million
Potential Savings	$162.1 million	$1.24 billion	$919.97 million	$2.89 billion
New Audit and Evaluation Recommendations	130	506	228	689
Recommendations Implemented by HHS Operating Divisions	265	432	181	286
Expected Investigative Recoveries	$1.44 billion	$3.00 billion	$1.37 billion	$3.14 billion
Criminal Actions	320	532	221	624
Civil Actions	320	689	272	791
Exclusions	1043	1689	1036	2148

Source: OIG HHS Semiannual Spring 2022, OIG HHS Semiannual Fall 2021, and OIG HHS Semiannual Spring 2021

HHS-OIG's Semiannual Report: Additional Key Findings

COVID-19 Pandemic Response

- COVID-19 lab tests drove an increase in total Medicare Part B spending in 2020
- Most state had implemented changes due to COVID-19 to ease restrictions on prior authorization and early refill requirements for prescription drugs.
- from March to the end of 2020, 84% of beneficiaries received telehealth services from providers with whom they had an established relationship



Preventing and Treating Opioid Disorder

- Roughly 1 million Medicare beneficiaries diagnosed with opioid use disorder in 2020, less than 16 percent received medication to treat their opioid use disorder
- Substance Abuse and Mental Health Services Administration's (SAMHSA's) oversight generally ensured that the commission on accreditation of rehabilitation facilities verified that opioid treatment programs met Federal opioid treatment standards.

Oversight To Better Protect Nursing Home Residents

- More than half of States failed to meet performance measures for oversight of nursing homes in three or four consecutive years during FYs 2015–2018
- OIG found that the current extent of facility-initiated discharges remains unknown

Reducing Costs to Beneficiaries for Part D Drugs

- Biosimilars have the potential to significantly reduce costs for Medicare Part D and beneficiaries.

Source: https://oig.hhs.gov/reports-and-publications/archives/semiannual/2022/2022-spring-sar.pdf

OIG to CMS: CMS can use audit reports to improve oversight of hospital compliance

The Office of Inspector General (OIG) performed a series of hospital compliance audits during calendar years (CYs) 2016 through 2018 to determine whether hospitals were billing appropriately and assessed the Centers for Medicare & Medicaid Services' (CMS's) actions.

OBJECTIVES OF THE AUDIT

- **Summarize the results**, after considering the status of appeals, of the OIG's hospital compliance audits covering Medicare claims paid from 2016 to 2018
- **Identify the actions CMS took** to implement OIG recommendations
- **Determine how CMS could improve program oversight** using OIG hospital compliance audits

RESULTS OF THE AUDIT

Out of the **387 improperly paid claims** across 12 previous hospital compliance audits:

$82M

In Total Overpayments received by the 12 hospitals after considering first and second levels of appeal

333

Inpatient Claims that result in **$5,260,147** in net overpayments

359

Overpayment Determinations remained, resulting in sustained overpayments totaling **$5,041,721.**

OIG RECOMMENDATIONS FOR CMS

The OIG was not able to verify whether CMS used the results from the issued audit reports and issued the following recommendations.

- Continue to follow up on the overpayment recovery recommendations contained in the audits covered by the above report
- Improve tracking and responding on the status claims identified as they proceed through the appeals process
- Direct CMS MACs to follow up with 8 of the 12 hospitals that have not responded to the recommendation to follow the 60-day rule or have not followed up at the conclusion of the appeals process (for those that are appealing the results of their audits)
- Revise CMS's SOP to require MACs to follow up with providers at the conclusion of the appeals process and require the MACs to provide additional detail to CMS regarding specific follow up actions taken
- Consider the results of this audit and future hospital compliance audits in its risk assessment process

Source: https://oig.hhs.gov/oas/reports/region4/42108084.pdf

Recent OIG/DOJ enforcement actions – key themes

Kickbacks

There have been numerous cases regarding submission of false claims to Medicare and Medicaid to induce their use of implantable cardiac devices, genetic tests, Durable Medical Equipment (DME), rehab services (by a skilled nursing facility), and beneficiary referral.

It is vital to keep educating physicians and leaders about the anti-kickback statute *and* making sure that organizations have a clear and independent process for identifying "preferred" devices.

Opioid abuse

Numerous issues have been identified related to illegal dispensing of controlled substances by either using fake/ stolen prescriptions or ignoring the red flags for addiction and abuse. There have also been cases involving lack of medical necessity for prescriptions.

Significant penalties and criminal proceedings were conducted in such incidences. Health systems need to be actively monitoring for opioids and drug diversion.

Facet joint injections

Submitting claims to Medicare for facet joint injections and denervation that exceeded the allowable number of or billing noncovered anesthesia services

OIG is utilizing data mining to identify potential coverage issues, and it's vital to have checks and balances to ensure the National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) criteria are met before submitting claims. This should be actively monitored as part of the compliance workplan.

Telemedicine

Telemedicine companies have intentionally paid physicians and non-physician practitioners kickbacks to generate orders or prescriptions for medically unnecessary services.

Telehealth services will continue to be audited/reviewed by governmental and other payers. Providers need to ensure there is medical necessity and that services are properly documented, coded, and billed.

Two-Midnight rule

OIG previously stated that it would not audit short stays after October 1, 2013. However, as of 2022, the OIG has provided notification that it will begin auditing **short stay claims** again, and when appropriate, recommend **overpayment collections.**

Many hospitals have more than a small number of short stays (0-1 day Length of stay) that are at risk for not meeting the two-midnight rule. Monitoring/auditing short stays should be a routine part of the compliance workplan in conjunction with utilization review.

Recent OIG CMS Audits – Key Themes

Diagnosis Codes

CMS relies on MA organizations to collect and submit diagnosis codes from their providers. Some diagnosis codes are at higher risk for being miscoded. There have been numerous cases regarding submission of diagnosis codes to CMS that do not comply with Federal requirements. This has resulted in millions of dollars in overpayments.

It is vital that healthcare providers continue to examine their existing compliance procedures to identify areas where improvements can be made. This can help ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements. Enhanced policies and procedures will help prevent, detect, and correct noncompliance with Federal requirements for diagnosis codes.

Provider Relief Fund

Providers that received the Provider Relief Fund (PRF) under the Phase 1 General Distribution are subject to requirements for submission of revenue information and attestation of acceptance or rejection of payments. OIG conducted an audit to determine whether HHS's and HRSA's controls related to selected PRF program requirements ensured that providers received the correct payments from the Phase 1 General Distribution.

While HHS and HRSA developed controls designed to ensure that providers received the correct PRF payments in a fast, fair, and transparent manner, some procedures were sill missing and could be improved. It is important that HRSA continue to perform post-payment quality control reviews of selected providers and seek repayment of any overpayments from providers. OIG also recommended that HRSA ensure that the HHS Program Support Center collects payments made to selected providers that did not return their rejected payments as of March 9, 2022. OIG provided a full list of recommendations filed under Health Resources and Services Administration.

Provider Compliance

OIG audited thousands of claims for dialysis and hospice services of selected providers to evaluate compliance with Medicare requirements. Records were submitted to independent medical review. OIG estimated that at least $14,193,6777 was received in unallowable Medicare payments for dialysis services, and at least $42.3 million in improper Medicare reimbursement for hospice services.

It is essential that providers strengthen their internal controls, policies, and procedures to ensure they comply with Medicare requirements.

Source:

1. https://oig.hhs.gov/oas/reports/region9/92003009.asp
2. https://oig.hhs.gov/oas/reports/region4/42108084.asp
3. https://oig.hhs.gov/oas/reports/region7/71901195.asp
4. https://oig.hhs.gov/oas/reports/region5/51800020.asp
5. https://oig.hhs.gov/oas/reports/region6/61909002.asp
6. https://oig.hhs.gov/oas/reports/region5/51900039.asp
7. https://oig.hhs.gov/oas/reports/region7/72106105.asp
8. https://oig.hhs.gov/oas/reports/region9/92106001.asp
9. https://oig.hhs.gov/oas/reports/region2/22001001.asp
10. https://oig.hhs.gov/oas/reports/region5/52000010.asp
11. https://oig.hhs.gov/oas/reports/region5/52000053.asp

Recent OIG Work Plan Items – Key Themes

Hospital Price Transparency

As of January 1st, 2021, CMS issues a final rule requiring hospitals, regardless of how they are paid, to make their prices readily available for consumers. CMS has outlined its monitoring and enforcement plan to ensure hospital compliance. Additionally, CMS has identified potential actions they may take for noncompliance, which include providing written warning listing violations, requiring a hospital to create a corrective action plan, and imposing civil monetary penalties.

OIG plans to evaluate CMS's monitoring process and enforcement of the hospital price transparency rule by reviewing whether CMS's controls are sufficient to ensure hospital pricing information is readily available to patients as required by Federal law. If hospitals are not in compliance, OIG will contact hospitals to determine the reason for noncompliance and determine whether CMS identified noncompliance and imposed consequences on the hospitals.

Medicaid Fraud

OIG provides oversight of Medicaid Fraud Control Units (MFCUs) and administers a Federal grant award to fund a portion of their operational costs. As part of their oversight, OIG annually recertifies each MFCU and assesses their performance and compliance with Federal requirements. As part of federal regulations, State contracts with managed care plans must require that potential fraud, waste, or abuse is promptly referred to MFCUs

It is vital that Medicaid Managed Care plans report Medicaid fraud to MFCUs and that MFCUs investigate and prosecute where necessary. OIG will issue an annual report analyzing information reported by MFCUs, describing the outcomes of MFCU criminal and civil cases, as well as identify trends in MFCU case results. Additionally, OIG may identify ways to increase the total number of managed care plan referrals, as there are concerns related to lack of referrals by Medicaid Managed Care plans.

Source:

1. https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000728.asp
2. https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000732.asp
3. https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000727.asp

Additional OIG Work Plan Items

Medicare Payments for Trauma Claims

CMS currently does not track which providers are designated or verified as trauma centers. There are ongoing concerns about trauma centers improperly billing for trauma team activation that is not medically necessary. OIG has also found that some trauma centers have received trauma team activation payments without proper designation or verification.

OIG plans to determine the amount of Medicare overpayments and charges that affect future hospital payments. OIG also plans to identify providers that are not trauma centers or that billed for medically unnecessary trauma team activations.

Inpatient Rehabilitation – Nationwide Audit

In fiscal year 2021, Medicare paid approximately $8.7 billion for 373,000 Inpatient Rehabilitation Facility (IRF) stays nationwide. OIG conducted a nationwide audit of IRF claims in 2018 and found that many IRF stays did not meet Medicare coverage and documentation requirements. OIG needs more information to better understand which claims IRFs believe are properly payable by Medicare.

OIG plans to determine whether there are areas in which CMS can clarify Medicare IRF claims payment criteria. OIG will also follow up on their prior recommendations from the 2018 audit. OIG stated that data and input from IRF stakeholders are critical to identifying any specific areas that might require clarification and will result in more meaningful recommendations and a greater positive impact on the program.

Source:
1. https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000742.asp
2. https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000740.asp

Pandemic Relief Funding – Oversight is Coming

Current Hot Topics

Pandemic Relief – With Massive Funding, Expect Massive Oversight

Pandemic Response Accountability Committee (PRAC):

- Oversees more than $5T in pandemic relief programs and spending
- Mission is to promote transparency and use data to detect fraud, waste, abuse, and mismanagement
- Created by the CARES Act to support and coordinate independent oversight of pandemic relief spending
- Membership includes 21 Inspector Generals, including the Health & Human Services IG Christi Grimm

Provider Relief Fund:

- HHS has distributed $86.3B to providers through general distributions, $55.8B to providers in targeted distributions intended to address specific areas of concern (e.g., nursing homes, children's hospitals), and $36B to support public health efforts (e.g., COVID-19 Uninsured Program, vaccine development)
    - Since February 2022, $9.8B of these funds have been returned
        - ❖ There is still uncertainty regarding how these returned funds will be used

Source: PRAC Releases A New Way To Show Pandemic Funding By Individual Federal Agencies | Pandemic Oversight

CARES Act/COVID Relief Funds

Background and Current Landscape

- The CARES Act required a platform to receive regular reports regarding the federal response to the pandemic (i.e., to monitor and oversee the federal government's efforts to prepare for, respond to, and recover from the COVID-19 pandemic)
- Three of the six COVID-19 relief laws appropriated a total of $178B to the Provider Relief Fund (PRF) to reimburse eligible providers for health care-related expenses or lost revenues attributable to COVID-19
    - The CARES Act appropriated $100B, the Paycheck Protection Program and Health Care Enhancement Act appropriated $75B, and the Consolidated Appropriations Act of 2021 appropriated $3B
- HHS recently announced $1.75B PRF payment distribution in April 2022
    - U.S. Government Accountability Office (GAO) report indicates PRF is "largely depleted" as of July 2022

Payment Integrity During COVID-19

- The Payment Integrity Information Act of 2019 defines improper payments as "any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements". Improper payments are a pervasive and growing problem in regular programs across the federal government
- They also have been a significant concern in pandemic spending, especially among the largest programs (e.g., unemployment insurance)
- Under guidance from the Office of Management and Budget, agencies are required to complete a risk assessment to determine a new program's susceptibility to significant improper payments after the first 12 months of program operations and, if susceptible, develop corrective actions and report on improper payments the following fiscal year
    - This means that improper payment information for new COVID-19 programs may not be reported until November 2022. By that time, agencies may have disbursed most, if not all, COVID-19 funds before assessing risk or developing corrective actions to address potential improper payment issues
- GAO suggested that Congress consider, in any future legislation, designating any COVID-19 relief funds that executive agency programs and activities making more than $100Min payments from COVID-19 relief funds as "susceptible to significant improper payment"

Sources: COVID-19: Current and Future Federal Preparedness Requires Fixes to Improve Health Data and Address Improper Payments and Provider Relief

Waivers and Flexibilities

Current Hot Topics

Coronavirus Flexibilities and Waivers

When the President declares a disaster or emergency under the Stafford Act or National Emergencies Act and the HHS Secretary declares a public health emergency, the Secretary may take certain actions in addition to their regular authorities

	Description of Waiver or Flexibility	Outlook
Telehealth Services Waivers	**Eligible Practitioners:** Expands the types of health care providers, i.e., physical therapists and occupational therapists, who may perform distant site telehealth services to include those that are eligible to bill Medicare for their professional services	The *Consolidated Appropriations Act of 2022* extended this flexibility for **151 days beginning on the first day after the end of the PHE**
	Audio-Only Telehealth for Certain Services: Allows the use of audio-only equipment, such as a smart phone, to provide services described by the codes for audio-only telephone evaluation and management services, and mental health counseling and educational services	
	Expanded Services: CMS has issued an extended list of services paid for by Medicare that may be provided via telehealth and geographic areas (as opposed to only rural areas)	
	Practitioner Location: Federally qualified health centers and rural health clinics may provide telehealth services to Medicare beneficiaries (i.e., may be distant site providers), rather than being limited to being an originating site provider for telehealth (i.e., where the beneficiary is located)	
	Provider Licensure: All states and D.C. temporarily waived various levels of state licensure requirements, so providers with equivalent licenses in other states may practice via telehealth	**Dependent on state**; in some states; these waivers are still active and tied to the end of the PHE, in others they have expired
	Telehealth for Mental Health and Substance Use: Medicare has permanently removed geographic restrictions for mental health and substance use services, allowing for beneficiaries to receive those services at home	**Permanently reimbursed** by Medicare (Consolidated Appropriations Act)
Home Health Agency & Other Medicare-Related Waivers	**Initial Assessments and Onsite Visits:** Allows HHAs to perform Medicare-covered initial assessments and determine patients' homebound status remotely or by record review. Additionally, CMS is waiving the requirements which require a nurse to conduct an onsite visit every two weeks	Postponed onsite assessments must be completed by these professionals **no later than 60 days after the expiration of the PHE**
	HHA Workforce Training: CMS modified the requirement home health agencies must confirm each home health aide receives 12 hours of in- service training in a 12-month period by postponing the deadline for completing this requirement	Continues until **the end of the first full quarter** after the PHE concludes
	COVID-Related Medicare Services: Beneficiaries participating traditional Medicare and Medicare Advantage (MA) pay no cost sharing for COVID- 19 at-home testing (up to eight tests per month), testing-related services, and certain treatments	Medicare will no longer cover COVID- related services at the **end of the PHE**
MA Coverage	**Out-of-Network Coverage:** MA Plans are required to cover services at out-of-network facilities that participate in Medicare, and charge enrollees who are affected by the emergency and who receive care at out-of-network facilities no more than if they had received care at an in-network facility	CMS recently proposed a revision to Medicare regulations**, ends 30 days after the latest applicable end date of the PHE and national emergency, or state disaster declaration**

Note: This is not an exhaustive list of COVID-19 related waivers and flexibilities.
Sources: Provider Enrollment and Certification, COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, and What Happens When COVID-19 Emergency Declarations End? Implications for Coverage, Costs, and Access

Coronavirus Flexibilities and Waivers

The end of the PHE will terminate access to certain regulatory flexibilities for providers and patients, specifically waivers for health care providers

AREAS OF FOCUS

Health care providers should inventory waivers and flexibilities deployed across lines of businesses before PHE expiration to proactively prepare for compliance. Waivers and flexibilities impacting many health care providers include those for promoting access to telehealth services, leniencies for prescribing practices, and relaxed requirements for practitioners

- **Telehealth:** Waivers allow for expansion of Medicare FFS telehealth services by increasing the types of practitioners eligible for providing and billing telehealth services and permitting audio-only equipment for select services. The Consolidated Appropriations Act of 2022 extended these flexibilities for 151 days beginning on the first day after the end of the PHE
- **Hospitals, Psychiatric Hospitals, and Critical Access Hospitals (CAHs), including Cancer Centers and Long-Term Care Hospitals (LTCHs):** Waivers allow for flexibility in hospitals, psychiatric hospitals, and critical access hospitals (CAHs) to reduce the administrative burden on providers and administrators, break down barriers to access to care, and decrease exposure points
- **HHAs and Hospice:** Waivers allow for HHAs to extend certain time frames on reporting, relax onsite visit requirements, reduce provider certification/ qualification requirements for certain services, and other waivers to reduce the administrative burden on providers and administrators (e.g., training requirements)
- **Psychiatric and Rehabilitation:** Waivers allow for flexibility in housing acute care, psychiatric, and rehabilitation inpatients outside of regularly distinct units and the reduction of IRF specific requirements
- **Comprehensive Care for Joint Replacement (CJR) Model:** Waiver modifies deadlines for participating hospitals to allow flexibility for repayment
- **Specific Life Safety Code (LSC) for Multiple Providers:** Waivers allow flexibility regarding prescriptive requirements for placement of alcohol-based hand-rub dispensers, the requirement for quarterly fire drills, and requirements that would normally not allow for temporary construction
- **Ambulance Services:** Waivers modify the data collection period and data reporting period for the Medicare Ground Ambulance Data Collection System and allow reimbursement for "Treat in Place"
- **Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS):** Waivers allow more flexibility for replacement of DMEPOS equipment by allowing DME Medicare Administrative Contractors to bypass the face-to-face requirement, a new physician's order, and new medical necessity documentation
- **Practitioners/Provider**: Waivers relax several requirements for practitioners, including allowing licensed practitioners to practice in states for which they are not licensed and modifying enrollment requirements

Note: This is not an exhaustive list of COVID-19 related waivers and flexibilities.
Sources: Provider Enrollment and Certification, COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, and What Happens When COVID-19 Emergency Declarations End? Implications for Coverage, Costs, and Access

Telehealth and Virtual Care

Both regulator actions and the COVID-19 pandemic spurred **changes in care delivery** and the connection of health data, resulting in **downstream shifts** in operating, reimbursement, coverage, and consumer engagement models. There is broad support from the health care community and consumers to continue with the recent advances in **meeting patients where they are**

Telehealth Metrics

- There was a 63-fold increase in the number of Medicare telehealth visits from 2019 to 2020 (~840,000 visits to ~52.7M visits) with Behavioral Health services accounting for the largest growth across service offerings
- Telehealth use increased by 19% for general outpatient visits between 2019 and 2021
- Out of the 272 telehealth services currently being reimbursed by Medicare, 99 will no longer be payable five months after the end of the PHE and 64 are temporarily payable through 2023

Home Health

- The number of home health episodes grew in 2020. Medicare (Part A and B) Home Health Episodes rose from 6.37 million in 2019 to 9.39 million in 2020
- The top four ICD-10 diagnoses of 2020 Medicare home health care recipients were Type 2 diabetes mellitus, Encounter postprocedural aftercare, Orthopedic aftercare, and Pressure ulcer treatment

On Demand Primary Care

- 54% of 18-29 and 51% of 30-49 age groups prefer after-hours access over weekend access
- 50-65+ age groups prefer weekend access over after-hours access

Virtual Visits

- 18-29 age groups prefers video enabled delivery channel while 30+ age groups prefer visits by phone
- Estimates indicate virtual-first plans have the potential to save employer's overall health care spend by 10%-30%

Sources: Medicare Beneficiaries' Use of Telehealth in 2020: Trends by Beneficiary Characteristics and Location, Telehealth Use Dropped to 8% in 2021, List of Telehealth Services, Home Health Chartbook 2021: Prepared of the Alliance for Home Health Quality and Innovation (AHHQI), How Consumers' Health Care Preferences Vary by Age, and 3 Takeaways from the Rise of Virtual-First Health Plans

Looking Ahead – Regulatory Landscape

Current Health Care Landscape

Despite the urgency of day-to-day pressures, **leaders should not lose sight of long-term capital and strategic planning.**

Hospitals and other healthcare entities are experiencing some of the worst margins of the pandemic

Seven months into 2022, organizations accrued enormous losses, but federal funds to offset the damages have been spent

Margins plummeted

July reversed gains hospitals saw this year and labor expenses rose

Outpatient activity dropped

An increasing number of patients continued to choose ambulatory centers over hospital settings for surgical procedures

Labor expenses increased

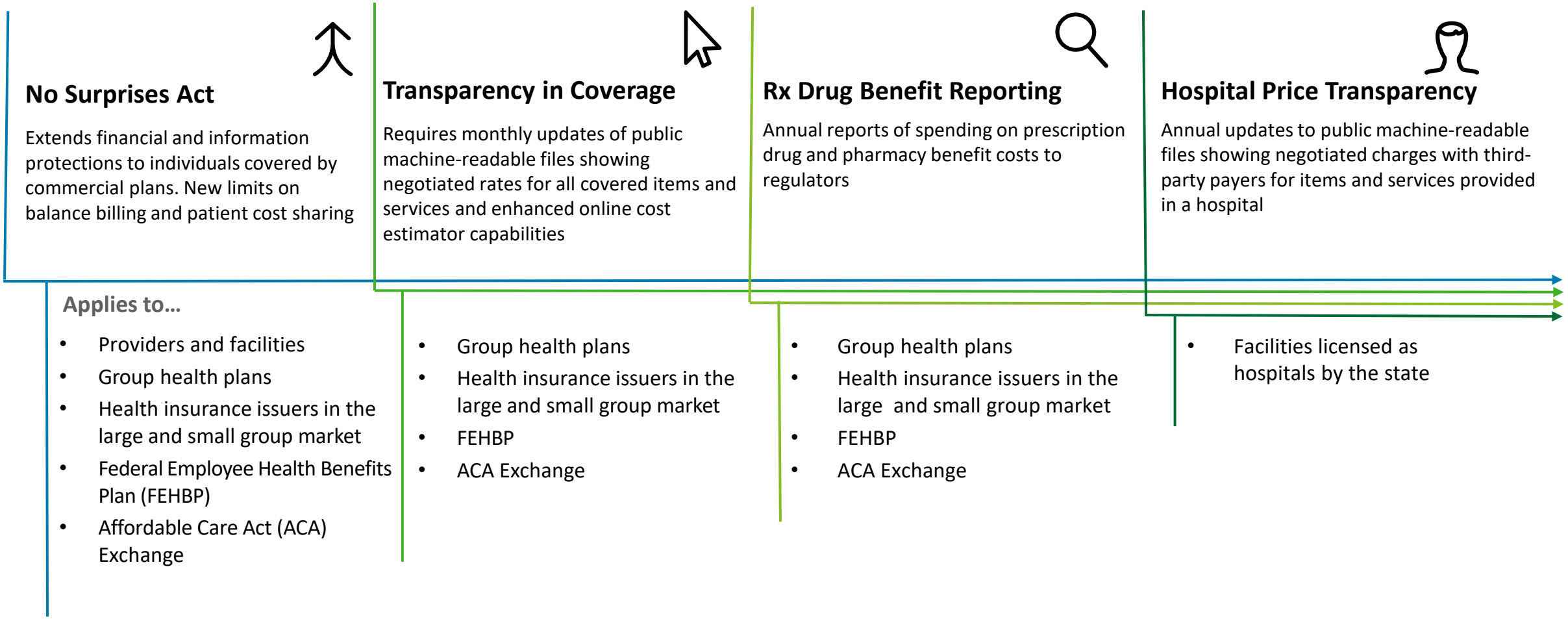
- Hospitals hired more aggressively, but labor was still in high demand, and prices rose
- Sicker patients stayed in the hospital longer, also driving up costs

Remote work increased employee morale

While health care has one of the lowest rates of remote workers, non-patient facing staff have shown to be more productive, experiences less burnout, and have higher morale when working remotely

Sources: National Hospital Flash Report August 2022 and As Practices Turn to Remote and Hybrid Work Models, Engagement and Culture are Key Considerations

Interrelated Regulatory Initiatives are Driving Consumerism and Competition in Health Care



Source: FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49

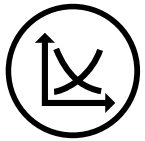
The Inflation Reduction Act (IRA)

"The IRA is a historic piece of legislation. There hasn't been such consequential legislation addressing drug costs since the passage of the Medicare Modernization Act in 2003, establishing the original drug benefit in Medicare nearly 20 years ago."

- Anne Phelps, Principal
US Health Care Policy Leader
Deloitte & Touche LLP

Drug Price Negotiation

For the first time in the history of the Medicare drug program, the Centers for Medicare and Medicaid Services (CMS) will now be required by law to negotiate directly with pharmaceutical manufacturers to control the rising prices of certain high-cost drugs in Medicare Parts B and D



Inflationary Price Caps

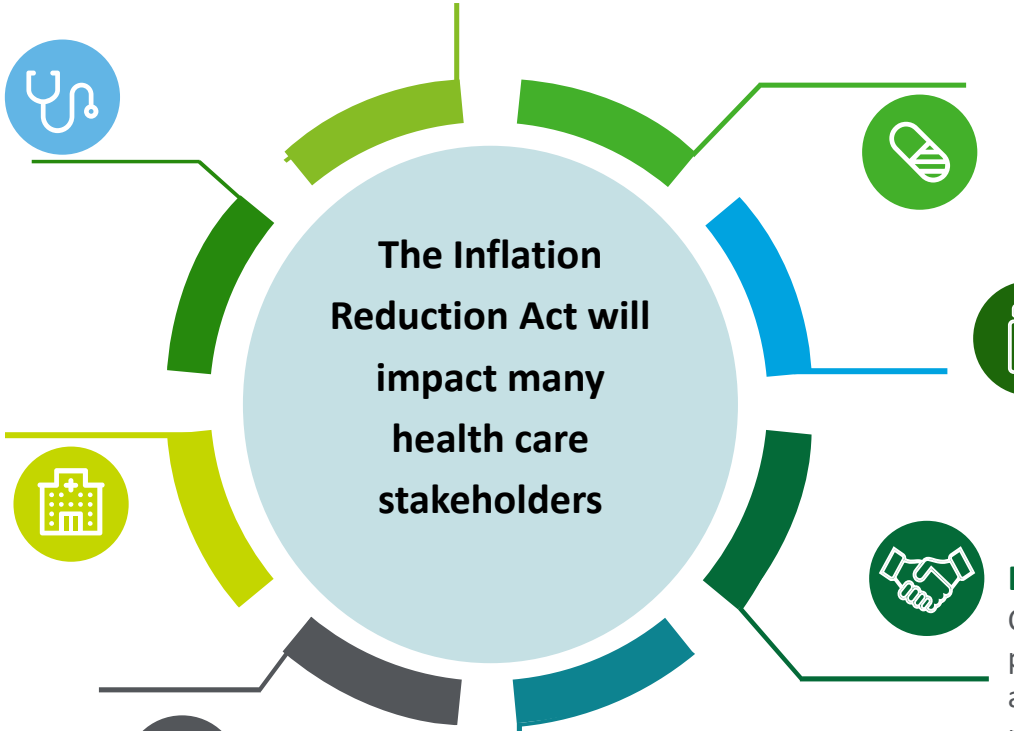
To help control the rising cost of medication for Medicare beneficiaries, **the law's inflationary provisions on Parts B and D drugs "cap" drug price annual growth rates** benchmarked against the Consumer Price Index for All Urban Consumers (CPI-U)

Medicare Beneficiaries

The law's drug pricing provisions aim to help Medicare beneficiaries by instituting measures to control rising drug costs while **lowering the existing maximum out-of-pocket under Part D, thus closing the so-called Medicare "donut hole" created under the original law in 2003**

Source: H.R.5376 - Inflation Reduction Act of 2022

The IRA's Broader Impact



DRUG MANUFACTURERS
Implications for drug manufacturers of high-cost medications will be critical focus, in addition to inflation rebates. Manufacturers will need to establish processes to analyze financial impact, conduct negotiations with CMS, and adjust agreements with customers

HEALTH PLANS
MA, MA-PD, and PDP* plans will be able to forecast drug cost impact on premiums, including future inflationary increases, and plan for increased costs in catastrophic coverage for beneficiaries

PHARMACEUTICAL BENEFIT MANAGERS (PBMs)
Price provisions and new negotiations may cause PBMs to analyze potential price shifts across Parts B, D and commercial markets

HOSPITALS / PROVIDERS
Reduction in high-price drug costs may benefit purchasing prices, while potentially decreasing revenue / margin for certain providers with higher Part B drug utilization (e.g., HOPDs**, infusion centers). Additionally, 340B programs will have to analyze maximum fair price negotiations against existing 340B discounts

PHARMACIES
Purchasing and supply chain impacts may benefit pharmacies, while price constraints could have longer-term impacts to revenue growth

EMPLOYERS
Commercial plans are not included in the drug pricing provisions. Medicare price reductions may cause cost shift and/or reevaluation of drug prices in the commercial market

HOME HEALTH
Providers administering home infusion or other medications may need to examine Part B revenue implications

MEDICARE BENEFICIARIES
Out-of-pocket costs for Parts B and D generally reduced and future increases to the growth of base premiums are limited to 6% per year

CMS

- CMS is appropriated $3B to establish the Drug Price Negotiation Program, almost double current program management funding
- CMS will need to issue regulations as soon as late 2022 / early 2023 to meet legislative timelines

Source: H.R.5376 - Inflation Reduction Act of 2022

*Medicare Advantage plans, Medicare Advantage Prescription Drug Plans, and Medicare Part D prescription drug plans

**Hospital Outpatient Departments

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This forum provides healthcare executives, including compliance and revenue cycle leadership, the opportunity to **hear updates on current regulatory compliance hot topics**, **share experiences** with industry peers, and learn from those who have developed **strategies for addressing both existing guidelines and changing or new regulations**.

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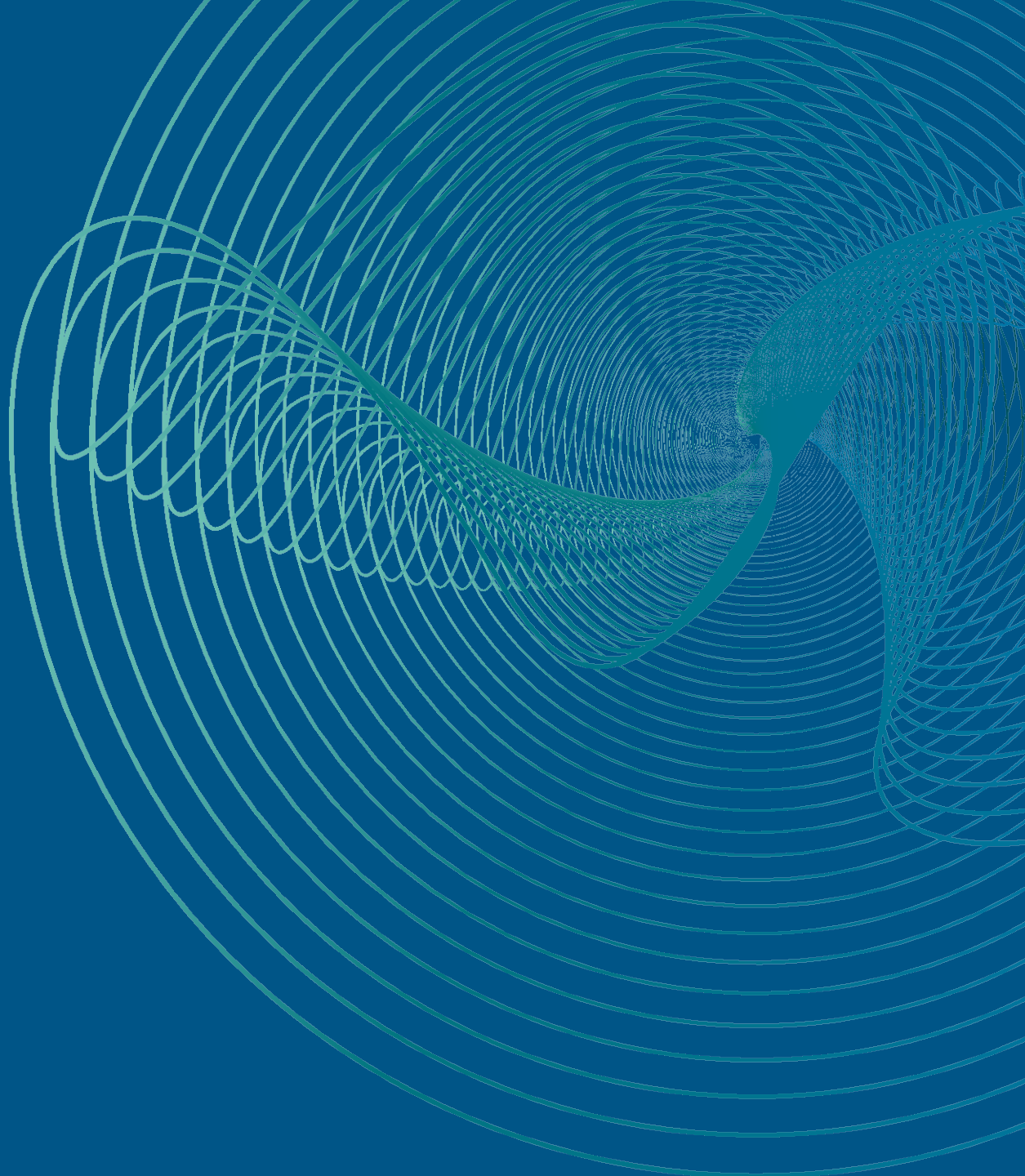

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