New Items in the OIG’s Work Plan Update - June 2019

The Office of Inspector General (OIG) has published the latest additions to its Work Plan. PYA offers insights on 16 noteworthy items, including inspection processes, the management of opioid use, and denials and appeals related to prescription drugs.

Background

Each month, the OIG publishes the most recent additions to its Work Plan. The work plan development process is dynamic and requires adjustments throughout the year to meet the OIG’s “priorities and to anticipate and respond to emerging issues with resources available.” With a goal of transparency, the OIG updates its Work Plan website monthly, outlining recently added information. The following is a summary of some of the latest additions, the agencies affected, and what they mean for compliance leaders in healthcare organizations.

Review of Centers for Medicare & Medicaid Services’ (CMS) Strategic Communication Contracts (CMS)

According to the OIG Work Plan update:

The Federal Acquisition Regulation (FAR) guides the acquisition process by which executive agencies of the Federal Government acquire goods and services by contract with appropriate funds. [The U.S. Department of Health and Human Services (HHS)] Acquisition Regulation establishes acquisition policies and procedures that implement and supplement the FAR. OIG is reviewing CMS’s awarding of contracts for strategic communications work. We will determine compliance with applicable Federal statutes, regulations, and HHS policies and procedures.

What You Need to Know:

One goal of CMS quality initiatives is to promote effective communication and coordination of care with the objectives of better care, healthier people, healthier communities, and smarter spending. In order to effectively and efficiently message the programs used to achieve these objectives, CMS contracts with communication vendors.

CMS, like all federal agencies, is required to follow guidance from the FAR when contracting for
strategic communications. The HHS acquisition policies and procedures provide implementation information that supplements the FAR guidance.

In June 2019, CMS released 16 strategic initiatives to deliver better value and results for patients, including price transparency, responses to the opioid epidemic, and innovative payment models. Providers can expect to see these initiatives communicated in a variety of methods through various communication outlets, partnerships, and tools.

Review of the Food and Drug Administration’s Foreign Drug Inspection Process (FDA)

According to the OIG Work Plan update:

The Food and Drug Administration (FDA) is responsible for overseeing the safety and effectiveness of all drugs marketed in the United States. However, FDA’s oversight of the nation’s drug supply chain has become increasingly complicated because many drugs used in the U.S. are manufactured overseas. FDA estimates that nearly 40 percent of finished drugs and approximately 80 percent of active pharmaceutical ingredients are manufactured in registered establishments in more than 150 countries. To ensure that drugs are manufactured in compliance with current good manufacturing practice regulations, FDA conducts inspections of foreign facilities that manufacture drugs for the U.S. market. At the end of an inspection, observations are made and a determination of whether any condition or practice violates Federal requirements. FDA may take additional actions to ensure that the violations are corrected. In May 2017, FDA began implementing major programmatic changes to enhance its ability to protect public health. FDA’s major programmatic changes included a structural realignment of its Office of Regulatory Affairs (ORA) and an agreement between FDA’s Center for Drug Evaluation and Research and ORA that aligns and coordinates FDA’s field professionals who conduct inspections and its review staff who evaluate drug products. Recently, Congress raised concerns about the safety of certain drugs manufactured overseas and the challenges that FDA faces with its foreign drug inspection process. Our review will determine whether recent programmatic changes have improved FDA’s foreign drug inspection process.

What You Need to Know:

While the FDA has implemented major program changes, increasing concerns over the possible lack of quality inspections performed by the FDA still exist. In July 2018, the FDA recalled the drug Valsartan, which was contaminated with NDMA, a probable human carcinogen. This led to discoveries of other contaminated drugs that had been used in the market. Further complicating the issue, the FDA redacted some of the originally released recall documents, one of which outlined an inspector’s concerns from a visit to one of the drug manufacturers in May 2017. Lawmakers and government committees are pushing for more investigation into these inspection deficiencies.

The FDA is making inspection results more open and accessible to the public, with the goal of increasing transparency about inspection outcomes and compliance issues. The aim of access to more current inspection reports is to enable FDA and other regulators to issue important alerts, warning letters, and recalls more efficiently in order to prevent repeat violations. Providers must stay up to date on all drug recalls published by the FDA and must have processes in place to take action when a recall occurs.
Opioid Use in Medicare Part D in 2018 (CMS)

According to the OIG Work Plan update:

The opioid crisis remains a public health emergency. In 2017, 47,600 opioid-related overdose deaths occurred in the United States. Identifying patients who are at risk of overdose or abuse is key to addressing this crisis. This data brief will provide 2018 data on Part D spending for opioids, as well as on beneficiaries who received extreme amounts of opioids through Part D and those who appeared to be doctor shopping. It will also provide data on prescribers who ordered opioids for large numbers of these beneficiaries.

What You Need to Know:

When opioids were first prescribed, distributors gave no warning about their addictive properties. It wasn’t until increasing rates of overdose and misuse became apparent that prescribers and the public caught on. At that point, the crisis was already underway. As stated in the Work Plan, 47,600 opioid-related overdose deaths occurred in the United States in 2017. Here are some additional National Institutes of Health (NIH) facts regarding the crisis:

- Roughly 21% to 29% of patients prescribed opioids for chronic pain misuse them.
- Between 8% and 12% of patients prescribed opioids for chronic pain develop an opioid use disorder.
- An estimated 4% to 6% who misuse prescription opioids transition to heroin.
- Approximately 80% of people who use heroin first misused prescription opioids.
- Opioid overdoses increased 30% in 52 areas in 45 states from July 2016 through September 2017.
- The Midwestern region saw opioid overdoses increase 70% from July 2016 through September 2017.
- Opioid overdoses in large cities increased 54% in 16 states from July 2016 through September 2017.

The NIH also outlined HHS’s five major priorities regarding this crisis:

- Improving access to treatment and recovery services.
- Promoting use of overdose-reversing drugs.
- Strengthening understanding of the epidemic through better public health surveillance.
- Supporting cutting-edge research on pain and addiction.
- Advancing better practices for pain management.

Some NIH efforts to assist in solving the opioid crisis include finding alternative pain-management treatments, such as physical therapy, acupuncture, massage, and other relaxation techniques. Other strategies might involve improving programs aimed at preventing overdose and reversing the disorder.³

Review of Medicare Part B Claims for Intravitreal Injections of Eylea and Lucentis (CMS)

According to the OIG Work Plan update:

Medicare Part B covers ophthalmology services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Ophthalmology services include intravitreal injections of Eylea and Lucentis to
treat eye diseases, such as wet age-related macular degeneration. Medicare pays for an intravitreal injection (which is considered a minor surgery) as part of a global surgical package that includes the preoperative, intraoperative, and postoperative services routinely performed by the physician. Medicare pays for Eylea and Lucentis separately from the intravitreal injection. Chapter 12, section 40.1 of the Centers for Medicare & Medicaid Services’ Medicare Claims Processing Manual states that separate payment can be made for other services provided by the same physician on the same day as the global surgery if the services are significant and separately identifiable or unrelated to the surgery. We will review claims for intravitreal injections of Eylea and/or Lucentis and the other services billed on the same day as the injection, including evaluation and management services, to determine whether the services were reasonable and necessary and met Medicare requirements.

What You Need to Know:

Providers can often find themselves incorrectly billing for additional services provided on the same day of a minor procedure when those services were already included in the procedure. When billing for additional services, providers must ensure the documentation clearly supports the medical necessity and states the separate and identifiable nature of the service from the minor procedure. All procedures, both minor and major, incorporate a necessary evaluation of the affected area. Therefore, most Evaluation & Management visits on the same day as a minor procedure are not separately billable, unless the provider can show the necessary reasoning for performing a more extensive or separate evaluation than what would normally be performed.

In the instances of the Eylea and Lucentis injections, the OIG is reviewing cases to verify whether any of the additional services performed on the same day as the injections were in fact significant and separately identifiable from the injection and therefore warrant billing, or were otherwise completely unrelated.

A process should be in place to review provider documentation to ensure that it supports the billing of additional services, as necessary. Keep in mind that documentation alone is not the sole factor in determining the ability to bill for additional services—clear medical necessity must also be established. For example, a documented full, comprehensive eye exam performed on an established patient who comes into the office for a planned injection is not automatically billable, even if he/she meets the coding requirements for a comprehensive exam.

Quality of Medicaid Encounter Data (CMS)

According to the OIG Work Plan update:

Effective oversight of Medicaid requires a national Medicaid dataset. Although all States submit Transformed Medicaid Statistical Information System (T-MSIS) data, OIG has consistently identified deficiencies in the quality of managed care encounter data, including inaccurate and missing information, which can render the data of limited use. We will determine whether the encounter data for selected States contain the required elements and include the quality data needed to more effectively oversee the Medicaid program. We will also determine what steps these States have taken to ensure that all required data elements are submitted to T-MSIS and identify any factors that contributed to data quality issues. This study will be based on a review of three to five States.
What You Need to Know:

T-MSIS data is crucial information necessary for CMS to properly oversee Medicaid and Children’s Health Insurance Program (CHIP) initiatives, as well as to evaluate program performance by providing a collection of beneficiary information, billing/claims data, and financial aspects.

A recently published Information Bulletin from CMS outlines 11 new priorities (in addition to the original 12) that states are expected to follow when submitting their data along with a timeline for completion aimed at November 2019.

Utilization and Pricing Trends for Naloxone in Medicaid (CMS)

According to the OIG Work Plan update:

Opioid abuse and overdose deaths are at epidemic levels in the United States. In response, both the U.S. Surgeon General and CMS have stated that increasing access to naloxone, especially among members of the public who are at risk or who know someone at risk, is a top priority. Naloxone is a medication designed to rapidly reverse opioid overdose. However, many stakeholders have expressed concerns that the high cost of naloxone may impede increased access. Medicaid could play a significant role in addressing the issue of naloxone access because the program covers nearly 40 percent of nonelderly adults with opioid addiction. The proposed data brief would (1) trend utilization of and expenditures for naloxone in Medicaid over a 5-year period; (2) determine how the cost-per-dose for naloxone under Medicaid compares to other available prices; and (3) determine the proportion of all naloxone distributed in the U.S. that was paid under Medicaid between 2014 and 2018. This information can help stakeholders determine how to cost-effectively increase naloxone access to affected Medicaid-eligible beneficiaries.

What You Need to Know:

With the current opioid crisis in the U.S., the NIH has begun making efforts to reduce the high number of opioid abuse and opioid-related overdose cases. One of the NIH’s current five priorities for the FDA is to promote the use of overuse-reversing drugs, such as naloxone. The three sets of data listed above would assist the NIH in promoting naloxone use by establishing the necessary cost-effective ways to make naloxone more accessible.

Involuntary Transfer and Discharge in Nursing Homes (CMS)

According to the OIG Work Plan update:

The involuntary transfer or discharge of a resident of a nursing home can be unsafe and a traumatic experience for the resident and his or her family. To address these concerns, Congress passed the Nursing Home Reform Act of 1987 to protect residents against involuntary transfer and discharge. However, data from the National Ombudsman Reporting System show that from 2011 through 2016, the Long-Term Care Ombudsman Program, established to advocate for older Americans by the Older Americans Act of 1965, cited complaints related to “discharge/eviction” more frequently than any other concern. In addition, the media has recently highlighted the rise in nursing home evictions. CMS estimates that as many as one-third of all residents in long-term care facilities are
involuntarily discharged. We will determine the extent to which State long-term care ombudsmen address involuntary transfers and discharges from nursing homes and the extent to which State survey agencies investigated and took enforcement actions against nursing homes for inappropriate involuntary transfers and discharges. We will also examine the extent to which nursing homes meet CMS requirements for involuntary transfers and discharges.

What You Need to Know:

The Nursing Home Reform Law of 1987 requires that nursing homes provide one of the following reasons as the need for a transfer or discharge:

- The nursing home cannot provide adequate care for the resident.
- The resident’s health has improved to the point that he or she no longer needs nursing home care.
- The safety of individuals in the facility is endangered.
- The resident has failed to pay for care.
- The facility ceases to operate.

In addition to these necessary reasons, the law also requires that a 30-day-minimum advance written notice, which also includes specific details regarding the discharge/transfer, be provided to the resident or applicable party.\(^5\)

Organizations with nursing home oversight should review relevant policies and processes regarding transfers/discharges to ensure they align with requirements.

Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries—10-Year Update (CMS)

According to the OIG Work Plan update:

OIG has conducted studies about adverse events (patient harm) in various healthcare settings since 2008, with 15 reports released or in process through 2019. The series includes a congressionally-mandated study released in 2010 that found that 27 percent of Medicare beneficiaries experienced adverse events or temporary harm events while hospitalized in 2008. The current study will replicate the methodology used in the prior work for a sample of Medicare beneficiaries admitted to acute-care hospitals in 2018. We will measure the incidence of adverse events and temporary harm events, the extent to which the harms were preventable given better care, and the associated costs to Medicare. We will compare the 2018 results with the prior study results to assess progress in reducing harm at the 10-year mark, and identify differences in harm rates, types, contributing factors, preventability, and costs.

What You Need to Know:

The OIG study published in 2010 reviewed a sample of 780 Medicare beneficiaries who were discharged in October 2008. The OIG researched the occurrence of any adverse events, compared any discovered events to the National Quality Forum (NQF) list of Serious Reportable Events and the Medicare list of hospital-acquired conditions (HAC), assessed the extent of harm incurred by the patient, determined if the event could have been prevented, and concluded the resulting cost to Medicare.
As stated above, 27% of those patients experienced adverse events or temporary-harm events (13.5% and 13.5%, respectively). The resulting cost to Medicare is estimated to have been around $324 million. The study found that 44% of these events could have been prevented.\(^6\)

With almost half of the events deemed preventable, the goal for HHS agencies is to establish hospital quality and safety measures that will promote better patient care and reduce medical errors. Organizations should review current practices to align with suggested practices from HHS.

**Blood Lead Screening Tests, Follow-Up Services, and Treatment for Medicaid-Enrolled Children (CMS)**

According to the OIG Work Plan update:

There is no safe level of lead exposure for children. In the absence of timely screening, follow-up services, and treatment, children remain vulnerable to cognitive deficiencies associated with lead exposure. Medicaid-enrolled children are required to receive blood lead screenings. Under the Early and Periodic Screening, Diagnostic, and Treatment program, children are also entitled to receive follow-up services and treatments for conditions identified through screenings (e.g., elevated blood lead levels [EBLLs]). Although previous OIG reports identified low rates of lead screenings, an evaluation of follow-up services for Medicaid-enrolled children with EBLLs has not been done. We will identify the percentage of children under 26 months of age who (1) received required blood lead screenings, (2) had EBLLs, and (3) received needed follow-up services and treatment. Additionally, we will determine why children with EBLLs did not receive screening, follow-up services, and treatment and the extent to which the Centers for Medicare & Medicaid Services provided guidance and technical assistance to States.

**What You Need to Know:**

According to Medicaid.gov, “…substantial environmental improvements have been made to reduce exposure to lead, [but] there are still over four million children estimated to reside in housing where they are exposed to lead. The Centers for Disease Control and Prevention (CDC) projects that there are about half a million children between the ages of one and five years in the United States who possess blood levels greater than 5 micrograms per deciliter (µg/dL), which is the threshold level at which CDC recommends public health actions are taken.”\(^7\) These findings indicate the necessity of blood screening tests. While there are Medicaid requirements for testing based on age and/or lack of previous testing, CMS is still working with the CDC to increase the rate at which these required tests are performed.

**Denials and Appeals in Medicare Part D and Medicare Advantage (CMS)**

According to the OIG Work Plan update:

Medicare Part D: CMS uses a capitated payment model to pay private insurers that provide and administer Medicare Part D benefits. Capitated payment models are on a payment-per-person rather than a payment-per-service basis, and they can create an incentive to deny access to services or payment in order to increase an insurer’s profits. Beneficiaries can appeal denied prescriptions and payments to multiple levels of review within the administrative appeals process. We will examine national trends and CMS’s oversight of prescription drug denials in Part D during 2014-2016. We will determine the extent to
which denials that have been appealed to each level of review were overturned. We will also examine variations in appeals and overturned denials across Part D contracts and evaluate CMS’s efforts to monitor and address inappropriate denials in Part D.

Medicare Advantage: Capitated payment models are based on payment per person rather than payment per service provided. A central concern about the capitated payment model used in Medicare Advantage is the incentive to appropriately deny access to, or reimbursement for, health care services in an attempt to increase profits for managed care plans. We will conduct medical record reviews to determine the extent to which beneficiaries and providers were denied preauthorization or payment for medically necessary services covered by Medicare. To the extent possible, we will determine the reasons for any inappropriate denials and the types of services involved.

What You Need to Know:

Medicare Part D Prescription Drug Program (Part D) requirements apply to stand-alone Prescription Drug Plan sponsors and to Medicare Advantage (MA) organizations that offer Part D prescription drug benefits. Part D plans are required to enter into agreements with CMS in which the sponsors agree to comply with a number of statutory, regulatory, and sub-regulatory requirements.

A Medicare enrollee has the right to contact his or her plan sponsor to make a specific complaint about the denial of coverage for drugs that the enrollee believes he or she is entitled to receive. Plans are required to classify complaints about coverage for drugs as coverage determinations, rather than a grievance or customer service inquiry. It is critical for a sponsor to properly classify each complaint in order for the enrollee to receive the required level of review.

A recent report from the OIG raises serious concerns about inappropriate MA denials of care, as well as wrongful payment denials. The report shows that MA plans—commercial health plans that contract with Medicare to deliver Medicare benefits—overturn their own denial decisions 75% of the time. Unfortunately, many claim denials are not challenged due to the lengthy, complicated appeal process. The biggest victims are the providers. The study found that 82% of the wrongful denials arose from appeals by providers for payment for services already rendered. Providers must have a process in place to analyze denied claims and implement denial prevention. Accordingly, a robust appeals process is critical to address denied claims and challenge payer recoupments for medically necessary services.

Financial Impact of Health Risk Assessments and Chart Reviews of Risk Scores in Medicare Advantage (CMS)

According to the OIG Work Plan update:

Under Medicare Part C, the Centers for Medicare & Medicaid Services (CMS) makes advanced monthly payments to Medicare Advantage (MA) organizations for each beneficiary enrolled. CMS risk adjusts these payments based on beneficiaries’ demographic information and clinical diagnoses from the prior year to pay MA organizations more for beneficiaries with higher expected costs. MA organizations submit to CMS encounter data, which are records of services provided to beneficiaries, including all diagnoses. Currently, CMS includes diagnoses from health risk assessments, which are visits to evaluate a beneficiary’s health risks, and chart reviews, which are records based on MA organizations’ review of beneficiaries’ medical records, when calculating risk scores and risk-adjustment
payments. This is allowed regardless of whether these diagnoses are supported by another service rendered to the beneficiary during that year. This study will determine the extent to which diagnoses solely generated by health risk assessments and chart reviews were associated with higher risk scores and higher MA payments. In addition, this study will determine the extent to which diagnoses removed by chart reviews were associated with risk scores and lower MA payments.

What You Need to Know:

Payments to MA organizations are heavily based on diagnoses; as such, it is crucial that providers correctly code and report all diagnoses so the information accurately reflects the beneficiary’s health status and medical needs.

An Issue Brief published by the Better Medicare Alliance details a few aspects of risk adjustment, such as the Coding Intensity Adjustment and two changes to the risk adjustment model that affect reported diagnosis codes. Using the Coding Intensity Adjustment, risk scores are reduced by at least 5.91% as of 2018, which ultimately reduces the payment made to MA organizations. This adjustment was put in place due to the distinct coding patterns between MA and Traditional Medicare. Two changes to the risk adjustment model include removing diagnosis codes for certain chronic diseases (announced in 2013) and a division of beneficiaries who are eligible for both Medicare and Medicaid into six groups based on their coverage and disability status (announced in 2017).

The Issue Brief notes that even with these changes, the risk adjustment model is still not an accurate reflection of the necessary costs required to treat chronically ill patients. Providers must verify that documentation and claims for health risk assessments, yearly well visits, and sick visits accurately report diagnosis codes for patients.

Comparison of Provider-Based and Freestanding Clinics (CMS)

According to the OIG Work Plan update:

Provider-based facilities often receive higher payments for some services than freestanding clinics. The requirements that a facility must meet to be treated as provider-based are at 42 CFR §413.65(d). We will review and compare Medicare payments for physician office visits in provider-based clinics and freestanding clinics to determine the difference in payments made to the clinics for similar procedures. We will also assess the potential impact on Medicare and beneficiaries of hospitals’ claiming provider-based status for such facilities.

What You Need to Know:

A study published by the OIG in 2016, titled “CMS Is Taking Steps to Improve Oversight of Provider-Based Facilities, But Vulnerabilities Remain,” aimed to confirm that facilities receiving higher payments due to their “provider-based designation” were in fact meeting the requirements necessary for that designation. As the study indicates, “…payments for services performed in provider-based facilities are often more than 50% higher than payments for the same services performed in a freestanding facility.” After finding a lack of benefit to Medicare, compared to incurred costs for services provided at provider-based facilities, the OIG has suggested no longer designating facilities in this way. It has also made recommendations and enacted laws to prevent higher payments to these facilities, but these measures have not caused changes across the board.
Home Health Compliance with Medicare Requirements (CMS)

According to the OIG Work Plan update:

The Medicare home health benefit covers intermittent skilled nursing care, physical therapy, speech-language pathology services, continued occupational services, medial social worker services, and home health aide services. For CY 2014, Medicare paid home health agencies (HHAs) about $18 billion for home health services. Centers for Medicare & Medicaid Services’ Comprehensive Error Rate Testing (CERT) program determined that the 2014 improper payment error rate for home health claims was 51.4 percent, or about $9.4 billion. Recent OIG reports have similarly disclosed high error rates at individual HHAs. Improper payments identified in these OIG reports consisted primarily of beneficiaries who were not homebound or who did not require skilled services. We will review compliance with various aspects of the home health prospective payment system and include medial review of the documentation required in support of the claims paid by Medicare. We will determine whether home health claims were paid in accordance with Federal requirements.

What You Need to Know:

The home care industry must be prepared for new or amended Federal, State, and/or Local obligations. It is critically important that providers have a comprehensive legislative tracking process and adopt proactive compliance strategies to both identify these changes and modify policies and procedures to conform to the new and updated requirements.

Home healthcare agencies must formalize their compliance functions by taking an active approach and adhering to best practices. If an agency with an effective plan in place finds itself with an overpayment situation, the OIG and U.S. Department of Justice are often willing to mitigate damages if a strong compliance function is apparent. Those agency compliance programs deemed most effective monitor and audit clinical records for payment requirements prior to submitting a claim. This practice reduces the likelihood of overpayments and minimizes risk.

On an operational level, providers must have processes in place to review necessary qualifications for billing home health services to ensure that the provider who is ordering the home health clearly documents the met qualifications. With the high error rate, mostly due to patients incorrectly listed as homebound, providers must understand the definition of homebound as provided by Medicare, which states that a patient who is homebound “[has] trouble leaving [the] home without help (like using a cane, wheelchair, or crutches; special transportation; or help from another person) because of an illness or injury.”

Access to Buprenorphine-Waivered Providers for the Treatment of Opioid Use Disorder (SAMHSA)

According to the OIG Work Plan update:

SAMHSA estimates that 2.5 million people have an opioid use disorder related to prescription pain relievers and/or heroin. Medication-Assisted Treatment (MAT), including buprenorphine, is a significant component of the treatment protocols for opioid use disorder and plays a large role in combating the opioid epidemic in the United States. Congress has taken sustained action to support MAT services through broadened prescribing authorities,
increased Federal funding, and insurance protections. However, a treatment gap continues to exist where less than 1 percent of the people in the United States who need treatment for substance use disorder receive it. OIG will examine access to MAT treatment through SAMHSA’s buprenorphine waiver program, which permits providers to prescribe buprenorphine to patients in office settings, rather than traditional opioid treatment facilities. We will examine the number, location, and patient capacity of providers who have obtained buprenorphine waivers from SAMHSA. We will also determine the extent to which waivered providers are located in areas with the greatest need for MAT services, the number of patients they report treating with buprenorphine, and the factors that may either facilitate or hinder the provision of buprenorphine in an office setting.

What You Need to Know:

As noted in similar OIG Work Plan reports addressing the opioid crisis, one of the OIG’s and NIH’s main goals is to make treatment for opioid disorders and overdoses more accessible. Buprenorphine is beneficial in that it not only treats opioid addictions, but also treats commonly related heroin addictions. However, like other medications in this group, access is limited, which is why the OIG is reviewing the possibility of expanding the ability to receive this drug when necessary.

FDA Oversight of Risk Evaluation and Mitigation Strategies to Address Prescription Opioid Abuse

According to the OIG Work Plan update:

Opioid abuse and overdose deaths are at epidemic levels in the United States. The Food and Drug Administration Amendments Act of 2007 provided the Food and Drug Administration (FDA) with the authority to require pharmaceutical companies to develop Risk Evaluation and Mitigation Strategies (REMS) when FDA determines that the risk of using a drug outweighs its benefit. Through the REMS program, FDA intends to “increase the number of prescribers who receive training on pain management and safe prescribing of opioid drugs in order to decrease inappropriate opioid prescribing.” We will describe how FDA determined the need for opioid REMS and determine the extent to which FDA has held pharmaceutical companies with required opioid REMS accountable for REMS assessments. We will also determine the extent to which FDA has held opioid REMS sponsors accountable for REMS goals to mitigate risks of misuse, abuse, addiction, overdose, and serious complications because of medication errors.

What You Need to Know:

Along with other goals set in place by the NIH, a high priority in responding to the current opioid crisis is to establish better educational opportunities for those prescribed opioid medications. The REMS program can assist with this, and the OIG report will describe the level of compliance that the FDA has required from pharmaceutical companies.

Part D Pharmacy Enrollment (CMS)

According to the OIG Work Plan update:

Since the inception of Part D, numerous OIG reports have raised concerns about Centers for
Medicare & Medicaid Services’ oversight of or actions to address fraud in the Part D benefit. Recent law enforcement actions have highlighted the role pharmacies can play in prescription drug fraud. When problems occur, Centers for Medicare & Medicaid Services must rely on Part D plan sponsors to follow up and take actions against pharmacies. Currently, Part D pharmacies are not required to enroll in Medicare. However, they may enroll for other reasons. For example, pharmacies that bill Medicare for durable medical equipment, prosthetics, orthotics, and supplies under Medicare Part B must enroll in Medicare Fee-for-Service. As a result, Centers for Medicare & Medicaid Services screens these pharmacies to ensure that they meet the requirements to be a Medicare provider. Centers for Medicare & Medicaid Services also has the authority to revoke their enrollment. We will review Centers for Medicare & Medicaid Services’ ability to oversee pharmacies that bill for Part D drugs and determine the extent to which pharmacies that bill for Part D Drugs, especially those identified as high risk, are enrolled in Medicare Fee-for-Service.

What You Need to Know:

Inappropriate billing is the most common type of fraudulent Part D incidents (e.g., submitting claims for drugs that were not provided) causing overpayments. Other potential risks for Part D fraud include Part D plans misrepresenting benefit offerings to CMS, pharmacies charging more than their usual and customary price for drugs, pharmacies improperly billing for brand-name drugs when prescriptions are actually filled with generic drugs, and the dramatic increase of billing for compounded topical drugs.

In accordance with the OIG compliance program guidance for Medicare+Choice (M+C) Organizations Offering Coordinated Care Plans, Part D plans must comply with all applicable statutory, regulatory, and other Part D requirements, including adopting and using an effective compliance program.

How PYA Can Help

PYA compliance consultants combine regulatory expertise with practical experience in healthcare organizations. Our compliance subject matter experts will provide a customized approach to assist you and your organization with today’s ever-changing compliance landscape.

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The M+C Program in Part C of Medicare was replaced by the MA Program pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173), enacted on December 8, 2003. Title II of the MMA made important changes to the M+C Program by replacing it with a new MA Program under Part C of Medicare. In conjunction with the new drug benefit provided by Title I of the MMA, changes made in the MMA to the MA Program included improvements to the benefit structure which now allows (and in some cases requires) most MA plans to offer Part D prescription drug coverage.