Your Guide to an Effective Compliance Program

Understanding the compliance programs needed to balance regulatory guidelines, member protection and business growth

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CRAFTED Rx SOLUTIONS

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Achieving Balance

Collaboration between the plan and its pharmacy benefit manager (PBM) is critical. In today's highly regulated environment, the PBM is in a unique position to serve as an extension of the plan's own compliance programs. The good news is that plans, healthcare providers, PBMs and government agencies all have the same goal: To ensure members receive the right care, at the right time and keep members' best interests in mind at all times.

An effective compliance program serves as an added layer of defense to ensure members remain a top priority. Regulations, quality and member experiences are all intertwined. Elixir provides unprecedented support of your approach to compliance by working with you to strategically balance the needs of your members, the needs of your business and the requirements of our government.

An Impactful Compliance Program Improves Outcomes and Your Bottom Line

The overall declining health of our population fueled by aging and chronic conditions, changes in government regulations and the shift in quality-based care have made healthcare in the United States overwhelmingly complicated.

A proliferation of complex, chronic conditions has given rise to costly specialty medications and increased the need to stabilize member health and prevent fraud, waste and abuse among members, prescribers and pharmacies.

In an attempt to control costs and improve quality of care, federal and state agencies continue to raise the bar through continuous auditing, regulatory oversight and ongoing monitoring. While these added requirements are designed to provide important safeguards for member and government spending, they add complexity. The Centers for Medicare and Medicaid Services (CMS) recognizes that "patients over paperwork" matter most, suggesting that regulations have become burdensome and lead to unintended member consequences. However, this makes achieving and maintaining compliance an ever-moving target—one with severe penalties if missed. Fines, membership loss and ineligibility to receive five-Star bonus payments are all consequences of noncompliance.

Enforcement actions can cost plan sponsors millions in monetary fines and, in some cases, suspend their ability to enroll members and grow their business. In 2021, CMS audited 27 plan sponsors, imposing sanctions on 13 sponsors based on 2021 referrals, and 16 civil monetary penalties (CMPs) totaling over $1,000,000.[1]

Conversely, as healthcare continues to shift from a fee-for-service to a pay-for-performance model, CMS rewards plans who do an exceptional job complying with defined quality standards. For government-sponsored plans, higher Star ratings can add new revenue in the form of Star bonus payments and extended enrollment periods that allow top-quality plans to accept new members year round.

Compounding this, health plans must also safeguard protected health information (PHI) at all costs, and keep a vigilant eye out for instances of fraud, waste and abuse (FWA). Sophisticated hackers, online scams and even those scouring trash dumpsters for printed information create a continuous threat to the theft of member PHI. Plans can be hurt financially, not only in the form of fines and penalties, but also through the lack of trust and decreased satisfaction of its members.

Like theft, FWA can rob a health plan of profits and force a plan into raising premiums and out-of-pocket expenses for members. Potential FWA can originate from members, prescribers or pharmacies, leaving health plans with the task of ensuring that medications are prescribed, dispensed and utilized properly to avoid waste and decrease abuse.

Delivering quality, affordable healthcare in a compliant way is an ongoing challenge for payers. Progressive health plans are partnering with experts to interpret and implement both regulatory requirements and growth strategies as a part of their pharmacy benefit programs. The result is an approach that successfully balances the needs of the business with the needs and rights of the members we care for every day.

[1] *2021 Part C and Part D Program Audit and Enforcement Report, Centers for Medicare & Medicaid Services. June 7, 2022.*

Your PBM: A Critical Partner

The PBM is in a unique position to help protect the plan's financial interests, safeguard member information and deliver quality care. Acting as an extension of your team, Elixir is engaged and can serve in a consultatory role, sharing knowledge of the regulatory landscape from a clinical and pharmaceutical perspective. We can also help ensure regulatory compliance and deliver quality care through flexible plan design.

With a team of industry leading compliance experts and world-class compliance programs, Elixir has built a reputation of trust and reliability in our industry. We take a comprehensive and proactive approach to compliance to help plans meet compliance goals, increase member satisfaction and make a positive bottom line impact.

Our approach to pharmacy care is built on a foundation of compliance, enabling us to focus on what we do—from plan design and formulary management to our pharmacy network and clinical support—to embrace industry best practices with a concentration on regulatory guidelines.

Five Things You Should Expect From Your PBM's Compliance Team

1 Reliability and Trust

Protect your business and the member

Elixir operates in a trustworthy and ethical manner, helping plans achieve governmental compliance, protect financial interests, safeguard member information and create a flexible plan with a focus on a positive member experience.

2 Bottom Line Impact

Deliver quality care and increase revenue

Compliance is more than just a cost of doing business, which is why at Elixir, our auditing, investigation and recovery services help protect your revenue and control costs. With a focus on quality member care, Elixir can design a program to grow your Star ratings and reimbursements.

3 Quality Assurance

Protect and prevent

Our proven programs ensure issue resolution from detection through correction, reveal patterns of fraud, waste and abuse, and provide enforcement standards and quality controls that safeguard PHI.

Daily monitoring occurs in business units, as well as oversight conducted by the Compliance & Ethics department, providing real-time potential for member impact. Elixir communicates these concerns to clients to avoid or minimize and remediate member impact and disruption.

4 Ongoing Insights

Compliance team expertise

Elixir acts as an extension of your compliance team, delivering insight and expertise to navigate the complex regulatory landscape and advance internal policies and best practices to achieve compliance goals. We are continuously engaged in government audits across our book of business and take the opportunity to share audit insight that may impact other plan sponsors. Elixir is committed to pursuing best practices and lessons learned from these experiences in order to mitigate risk for all plans.

5 Operational Flexibility

Establish and refine processes

Our operational flexibility allows us to align our compliance best practices with your business goals to achieve a confident approach to compliance. Payers can achieve and maintain governmental compliance with our compliance suite of services that fit their business needs.

OUR COMMITMENT

We are ethical and decent, accountable to each other and take responsibility for getting involved. We value making a difference and doing what's right, even when no one is looking.

A Regulatory Audit Shouldn't Mean Panic for Health Plans: What You and Your PBM Should Do To Be Prepared

Conducting your own internal audits can be critical to supporting compliance. By learning how to properly identify potential issues through risk assessments, conducting internal auditing and monitoring, properly utilizing technology, and preparing with mock audits, regulatory audits no longer need to be feared.

Risk assessments are a good starting point for taking the fear out of audits. With a risk assessment, you can:

- Identify areas of exposure or challenges
- Document the key controls, procedures and monitoring activities to safeguard against potential issues
- Develop further actions to mitigate risk exposures, if needed, and validate that processes are working

To start, an organization needs to identify its audit universes. These are the areas or functions a company utilizes to meet its objectives. As an example, a PBM's audit universe could include benefit setup/change, eligibility, fulfillment, claims adjudication, customer care, clinical operations, rebates, information security and accounting. Each area consists of key activities and procedures where risk assessments can be conducted to determine compliance and what is needed for the next internal audit cycle in order to mitigate risk.

The first step in conducting a risk assessment is to consult external or third-party reports, such as the SOC1, which is an independent examination that provides information on the effectiveness of controls that could affect a plan sponsor's financial reporting. It covers areas similar to the above PBM audit universes, providing examples for each component, as well as key financial reporting controls and testing results.

Elixir makes the SOC1 report available to all health plan clients as a resource. Because examinations, like the SOC1, are conducted by external parties, plan sponsors can obtain a higher level of comfort that controls are supporting effective risk mitigation.

It is also important to interact with people working on the frontlines when conducting a risk assessment. As an example, if you are doing a risk assessment of the prior authorization process, you should interview pharmacists and pharmacy technicians who actually perform prior authorization reviews. They are familiar with all of the potential issues and challenges and can provide the information truly needed to assess risk.

After applying information from third-party and frontline sources, a plan sponsor can look for any remaining gaps to determine what should be included in the next internal auditing cycle and where it might be appropriate to reassess effectiveness in the upcoming cycle. With a risk assessment, you want to look at what could go wrong and what's in place to stop that from happening.

Technology Lights the Way

We are seeing a paradigm shift away from the traditional auditing approach, where samples are selected at random and documentation is reviewed manually, to a more scientific approach utilizing data and technology. In fact, CMS is decreasing reliance on audits in favor of continuous auditing through desktop procedures. Now, when CMS requests periodic reports and universe files, it's not random because they're using technology to identify anomalies in data. This means you should be using technology to identify anomalies as well.

There are various tools available today to support this new approach of analytics and monitoring, including data management, visualization and monitoring software programs. These tools allow you to collect hundreds or even thousands of records from multiple sources into one repository. Queries or scripts can then be conducted to analyze the data. Once these queries are created, they can be repeated at regular intervals—weekly, monthly, quarterly—to develop a continuous desktop monitoring program. Visualization software can then be utilized to summarize the details in charts and graphs, rather than creating lengthy paper reports.

If the data do not meet the rules established from your criteria, there is a potential issue that should be investigated further and, if needed, an action plan should be developed. The results of your desktop monitoring program can then be reported using visualization software.

Practice Makes Perfect

While doing risk assessments and implementing a desktop monitoring program can help prepare you for a regulatory audit, we all know practice makes perfect. That's why it is important to conduct mock audits. A robust mock audit process ensures a continuous state of audit readiness.

To establish a mock audit program, use the following Lean process:

Plan: Identify the audit participants, define their roles and set expectations. This should include a primary and backup audit team with cross functional representatives, such as pharmacists, members from operational units and the Compliance department.

Do: Select difficult cases to ensure your audit team is ready for anything.

Check: Review the audit results, provide a final report and get feedback.

Act: Complete any necessary corrective actions and remediations, as applicable.

By identifying your risks, using technology to continuously monitor risk areas and conducting mock audits, your organization can feel prepared and sleep well at audit time.

Pharmacy Benefit Compliance: An Extension of Your Internal Compliance Program

Our professional compliance team consists of subject matter experts in health law, pharmacy, CMS program audits, fraud prevention, internal and external audits, as well as continuous monitoring. Through oversight, collaboration, innovation and education, we deliver client services with the highest standards of integrity, accountability and excellence. Our team provides expert insight, effective training and actionable strategies tailored to your organization's unique needs.

An Elixir Compliance Officer works hand-in-hand with your compliance and pharmacy teams to address compliance considerations before they become issues. In addition to designing workflows and processes to maximize effective and strategic outcomes, the Elixir Compliance Officer participates in calls and meetings, both internal and external, and interprets federal and state guidelines and regulations.

Maintaining compliance for Medicare and Medicaid requires a strong pharmacy benefits partner with the ability to interpret and adhere to regulatory guidelines.

Elixir provides the opportunity for health plans and their related business partners to participate in regular events where clients and compliance experts share best practices and discuss strategies to address industry trends and regulatory changes.

For commercial plans, rest assured that we will help you understand the regulations that impact you on the federal and state levels.

An Accomplished Team of Experts

Our subject matter experts provide a broad spectrum of experience to address any compliance challenge. Your Elixir compliance team includes the following credentials:

- Juris Doctor (JD)
- Doctor of Pharmacy (PharmD)
- Doctor of Health Science (DHSc)
- Doctor of Philosophy (PhD)
- Registered Pharmacist (RPh)
- Master of Healthcare Administration (MHA)
- Master of Public Health (MPH)
- Master of Business Administration (MBA)
- Fellowship in Academic Medicine
- Certified Compliance and Ethics Professional (CCEP)
- Certified Fraud Examiner (CFE)
- Certified in Health Care Compliance (CHC)
- Certified in Risk Management Assurance (CRMA)
- Certified Information Privacy Manager (CIPM)
- Certified in IDEA Data Analytics (CIDA)
- Certified Information Systems Auditor (CISA)
- Certified Internal Auditor (CIA)
- Accredited Healthcare Fraud Investigator (AHFI)
- Certified Information Privacy Professional (CIPP)
- Registered Pharmacy Technician (RPhT)
- Certified Pharmacy Technician (CPhT)
- Certified Public Accountant (CPA)
- Chartered Global Management Accountant (CGMA)

Achieving an Effective Compliance Program as a Team

The Programs, Services and Tools You Need

Elixir works as an extension of your team, providing the thought leadership, programs, services and tools you need to establish and maintain compliance in ways that positively impact your bottom line.

Compliance Operations

Simplifying the Complex

As government regulations continue to evolve, it can be complicated to keep up with the changes. CMS provides guidance in the form of memoranda, webinars and compendia to help health plans understand all regulation implications and improve adherence. Elixir helps plans make the most of these resources.

Regulatory Oversight

In 2022, CMS released 466 memos through the Health Plan Management System (HPMS). The volume of CMS memos, coupled with Medicaid guidance, Office of Inspector General (OIG) work plans and other state/federal regulatory changes make it difficult to stay ahead of transformations in the regulatory landscape.

The key to complying with ever-changing regulatory guidance is a proactive and consistent approach to tracking and responding to each and every guidance change. Elixir holds weekly workgroups to review, analyze and operationalize guidance to support continued compliance with regulation. We utilize multiple business areas, leveraging legal and compliance experts, as well as functional business unit subject matter experts. Through this detailed review of regulatory impacts to our plan sponsors and the PBM, we actively support our commitment to an effective compliance program.

Operational considerations include:

- Policies and procedures
- Monitoring and oversight practices
- Systems processes and configuration changes
- Crucial filing deadlines

In addition to weekly guidance reviews, more detailed analysis should include major CMS communications, such as:

- CMS Final Rule
- CMS Annual Part C and Part D Program Audit and Enforcement Report
- CMS Annual Readiness Checklist
- Ad hoc Chapter Guidance releases

Internal Oversight and Issue Resolution

Elixir recognizes the importance of overseeing plan sponsor-delegated functions to ensure potential issues are discovered in real time and promptly remediated. Each business unit that provides essential PBM-delegated functions has a dedicated partner within the Compliance department. This partnership ensures constant interaction to address new guidance, client inquiries, consider process improvements and monitor key performance indicators (KPIs) within the applicable business unit.

Compliance works with operational areas to ensure effective monitoring practices are in place. Oversight activities are performed and reported at periodic collaborative workgroups, as well as to leadership at the quarterly Compliance Committee. Elixir has documented the details of its extensive oversight activities in the Compliance Oversight Package. This collection of policies and procedures outlines the type, frequency and oversight specifics related to key PBM-delegated functions, providing the plan a clear sense of the oversight program in place at the PBM. Compliance oversight findings, coupled with internal audits and risk assessments, drive the annual Compliance department's work plan process, ultimately resulting in focused efforts where it matters most.

When a deficiency is identified, the business unit and compliance partner work in unison to remediate and develop a plan to correct and implement new processes to ensure the issue does not happen again. Furthermore, the compliance team monitors and performs a validation audit to ensure that corrective actions put into place are effective and prevent reoccurrence.

First Tier, Downstream and Related Entities

Plan sponsors can be assured that we will preserve and protect your compliance integrity with proper oversight of first tier, downstream and related entities (FDRs). Elixir has established policies and procedures to ensure compliance as a first tier entity to the plan and provides downstream entity oversight. Subcontractors or vendors are used sparingly, with robust monitoring and oversight practices in place.

Elixir performs annual audits of downstream entities and provides sponsors with reports identifying FDR administrative or healthcare functions carried out on the plan's behalf, including observations and corrective actions and a copy of the FDR's annual compliance attestation.

Elixir conducts regulatory risk assessments as part of its regulatory risk management program. The risk assessments identify and assess controls and other business disciplines that support effective risk mitigation for the regulatory areas. The regulatory risk management program includes auditing of these regulatory controls and business disciplines based on the significance of the regulatory area, including audits of FDRs.

The auditing and oversight includes a screening against the Health and Human Services (HHS) List of Excluded Individuals and Entities (LEIE), as well as federal and state-specific databases to ensure pharmacies, prescribers and pharmacists are all in good standing. Entities not in compliance are subject to disqualification from doing business with Elixir. Those that pass our corporate integrity validations must attest in writing that they have an effective, active compliance program in place.

Elixir conducts an FDR oversight program by providing subject matter experts and the tools and resources necessary to identify, designate, train, educate, track, monitor and assist FDRs on compliance-related matters.

Marketing Materials

Plans are held accountable for following more than 50 pages of CMS Medicare Communications and Marketing Guidelines (MCMG), as well as following model documents for member communications.

Where translations are required for templates or model documents, plans must translate the model or template language and the variable data that is populated at a later time.

When a third-party, such as a PBM, creates and distributes member-specific materials (e.g., explanation of benefits, explanation of payment, direct claim form) on behalf of multiple organizations, it is acceptable to use the material ID for only one organization.

Regarding mailing statements, when third-parties, such as PBMs, create and mail materials on behalf of multiple organizations, they are not required to use the specific plan name.

Elixir supplies health plans with all updated CMS model documents to assist in the creation of marketing and communication materials. We provide revised information on model language and required language to include in marketing materials so plans can achieve CMS approval and compliance.

Member Communication

As the number of regulatory requirements increases, compliance takes up more space in member communications. Elixir works on the plan's behalf to create member Part D communications that are compliant in form, substance, content and timeliness. Some examples include communications regarding coverage determinations, appeals and grievances (CDAG) and a transition policy for temporary fills.

In addition to providing plans with monthly reports on member call center compliance requirements, Elixir has established policies and procedures that meet all Medicare Part D requirements regarding member call center hours of availability, information and enrollment scripts, response and hold times, and disconnect rates.

Our clients can be assured that we are connecting with members in a friendly, transparent and compliant manner.

Medicare Applications and Plan Implementation

Submitting an application to seek a new Prescription Drug Plan (PDP) or Medicare Advantage-Prescription Drug Plan (MA-PD) contract, or to expand the service area of a current contract can be a daunting task. For organizations undertaking this task, Elixir has a Medicare Application Guide available that assists plans by populating the applicable PBM-related fields. It provides guidance in a question-by-question format that allows the organization to easily extract information relevant to their own application and final submission to CMS.

Leading up to each new plan year, Elixir takes a methodical approach to implementing the Medicare benefit for the coming contract year.

Each plan's Elixir-designated Compliance Officer is involved from start to finish, throughout the implementation and during the crucial first hours, days, and weeks following go-live. The compliance team is part of discussions with the plan and Elixir subject matter experts (SMEs) to ensure that the benefit design is compliant with regulatory requirements and all applicable Medicare guidance. Particular attention is paid to customizations that could lead to potential compliance risk. Once the new plan year begins, the compliance team works closely with the business units to oversee the ongoing monitoring performed to ensure a successful implementation.

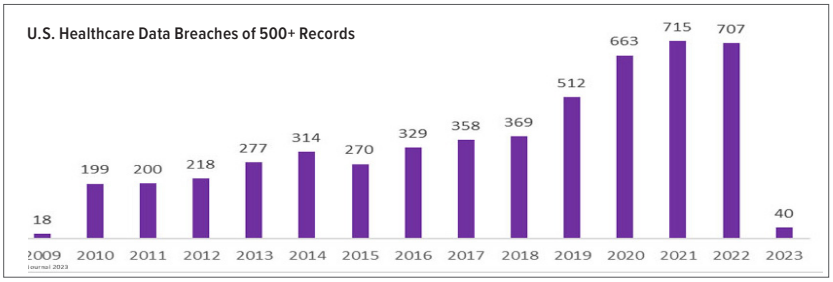
Privacy Operations

Protected Health Information

Data privacy and security are essential in the healthcare industry. Securing personal information depends on robust data protection programs and adherence to various laws and regulations, such as HIPAA. Healthcare data breaches and penalties continue to rise and a having a proactive strategy is critical.

Through our data governance framework and documented policies and procedures, Elixir's privacy and security operations are well-established. This allows us to effectively manage and safeguard data across our various systems and applications.

LARGE HIPAA DATA BREACHES BY YEAR[1]



Source: https://www.hipaajournal.com/2020-healthcare-data-breach-report-us/

Privacy

When it comes to privacy and security, plan sponsors continuously manage compliance with various federal and state requirements, including HIPAA and the Health Information Technology for Economic and Clinical Health (HITECH) Act.

A core function of the Elixir privacy program is to perform operations and oversight activities that ensure effective data protection practices and adherence to regulatory requirements. The Elixir Privacy team has broad experience and engages in a multitude of areas to protect your information by partnering with our clients and internal stakeholders, such as Information Security. This includes:

- Privacy and security contract management
- Personnel training, education and awareness campaigns
- Routine monitoring, oversight and auditing
- Collaboration on cybersecurity practices and infrastructure
- System and process implementation to quickly respond to allegations and complaints
- Ongoing incident response planning, risk assessments and mitigation plans
- Strategic management of compliance with privacy and security regulations and frameworks

As plans sponsors implement data privacy and security practices, Elixir's Privacy team can provide support. We can coordinate with you to align our policies and procedures, training programs and overall data protection program. This type of integrated approach is a priority for Elixir, as the regulatory landscape continues to advance, both in the U.S. and globally.

Developing a proactive strategy to privacy and security is critical. If an organization is already HIPAA-compliant and has good risk management practices, it will be positioned to successfully adapt to any new requirements. Through robust systems and compliance controls, Elixir offers innovative solutions to optimize your data protection program.

In 2022, healthcare data breaches of 500 or more records were reported at a rate of more than 1.94 per day.

Source: https://www.hipaajournal.com/healthcare-data-breach-statistics/

Enterprise Risk Managment

To stay abreast and to gain a critical perspective of emerging and changing risks, a practical approach for governing and managing enterprise risk is needed. The Enterprise Risk Management Program is a collaborative effort between Enterprise Risk, Legal, Operations, Compliance, and Internal Audit, and is designed to assess, remediate and validate key risks. To do this, risk assessments are conducted on an annual basis, and identified key risks are assessed for potential impact on the business. Based on the risk assessment results, Risk Management works with risk owners on remediation or enhanced action plans to help mitigate the potential risk. For significant risks, validations of risk control effectiveness are performed.

Internal Audit

With U.S. healthcare claims processing and payment errors costing plan sponsors billions of dollars, a reliance on audit services to provide assurance that compliance and operational controls are in place are a must.

Claims Adjudication and Financial Accuracy Audits

Based on risk or requests by management, Elixir conducts a performance guarantee audit across our book of business, which is designed to assess the financial and adjudication accuracy of submitted member claims. This includes testing the accuracy of ingredient costs, dispensing fees, member copayments, eligibility, drug coverage and deductible application.

The results of the audit are utilized to help maintain 99% or higher accuracy levels in claims adjudication and costs. To maintain a high degree of objectivity, the audits are conducted by our Internal Audit department.

Data Security

Security of your data is of the highest importance to us. To that end, Elixir established a security governance program in which Privacy, Security and Internal Audit teams work concertedly to support the protection of member PHI and personally identifiable information (PII) from physical, technical and operational security incidents using the ISO 27002 standard. The program partners with IT, the Compliance and Ethics department and operational units to maintain industry defined leading practices for effective data protection standards and procedures. Qualified, independent security resources are also utilized for testing the integrity of data protection.

Service Organization Control (SOC) Reports

Save time and money and provide assurance to your auditors that pharmacy benefit management and related administrative services have adequate controls in place. Elixir contracts with an independent firm to perform an annual examination of the internal procedures that could impact controls over your financial reporting.

Most financial auditors require plans to obtain an SOC 1 Type II report from their service organizations in order to form an opinion and complete the audit of financial statements. Auditors look for adequate controls relative to the plan's business partners.

Clinical Audit Services

Improved Patient Outcomes

The best time to prepare for an audit is before you receive a CMS audit engagement letter. CMS continues to increase the level of enforcement and penalties for compliance violations around clinical care, especially regarding coverage determinations and redeterminations. According to the 2017 Part C and Part D Program Audit and Enforcement Report, CMS indicated a “direct trend in the relationship between audit scores and Star ratings,” further demonstrating the relationship between compliance, quality of care and financial activities. Health plans that improve their clinical audit functions also improve patient outcomes and member satisfaction.

CMS Audits and Audit Preparedness

When an audit occurs, no one sleeps. A majority of the plan's resources are focused on supplying large amounts of data in required universe layouts. Accuracy of data is key. CMS allows plan sponsors only three attempts to submit accurate data for Coverage Determinations, Appeals, and Grievances universes and Formulary Administration universes. There is a high risk of incurring fines and sanctions for incorrect data, both of which can hurt businesses.

Elixir provides plan sponsors monthly universes of initial coverage determinations and redeterminations, including timeliness reviews, formatted in compliance with CMS' audit protocols, allowing Elixir to remain in a constant state of audit readiness.

When the time comes for an audit, Elixir partners with the plan sponsor through the entire process, beginning when CMS issues the audit engagement letter through the audit close-out. For delegated functions, Elixir prepares the universes in the required layout for the plan sponsor's review and takes the lead for these functions during the audit webinar. Elixir also works with the plan sponsor to develop and implement corrective action plans, if needed, and takes necessary steps to reassure the plan and CMS that deficiencies are corrected.

To maintain audit readiness, Elixir conducts mock audits following CMS audit protocols and timelines with 'How To' step-by-step audit processes and procedures. Each program audited functional area

has a defined audit team, as well as a back-up audit team for a seamless transition should a team member be unavailable. All participants are trained on best audit performance and each is assigned a defined role and responsibility.

Our Clinical Audit Compliance team acts as the auditors and the functional area team (in a separate location from the auditors) participates as the audited party. These mock audits are practice audits for the applicable functional areas of the PBM to run through audit scenarios and practice speaking and presenting to an auditor, and for the Compliance department to provide coaching for improvement to ensure Elixir remains in a state of CMS audit readiness.

Mock audits are mimicked as closely as possible to CMS program audits from the engagement letter to providing attendance sheets for each session to requesting deliverables using CMS timelines. Because these mock audits replicate CMS audit processes, conducting them helps improve processes and efficiencies, not to mention preparedness.

Medication Therapy Management (MTM)

To meet CMS requirements, plans must offer MTM to members who have multiple chronic conditions, take multiple medications and have high drug expenditures. In addition to establishing an MTM program, plans need to build MTM into their benefit structure and submit data results to CMS annually.

Our full service MTM program includes an annual comprehensive medication review and interventions for potential drug therapy problems. We keep plans up to date on CMS policies related to MTM with our weekly Health Plan Management System (HPMS) Memo Tracker. We also provide MTM annual reporting, formatted in the required layout for easy uploading to CMS.

Coverage Determinations, Appeals and Grievances (CDAG)

With changes to CMS Program Audit Protocols, Annual Reporting Requirements and Technical Specifications, plans may struggle to align with CMS requirements.

In order to help plans meet CMS requirements, Elixir monitors internal practices related to CDAG processes and provides key reports, such as:

- Monthly universes in CMS' table layout for standard audit protocols for coverage determinations and redeterminations (appeals)
- Monthly summary report of total coverage determinations and redeterminations requested by disposition and timeliness
- Annual coverage determinations and redeterminations report by quarter provided in CMS' technical specifications reporting requirements

In addition, we offer secure web portal access to view and monitor coverage determinations and/or redeterminations in real-time. This provides the plan with more in-depth monitoring and oversight of delegated services to the PBM.

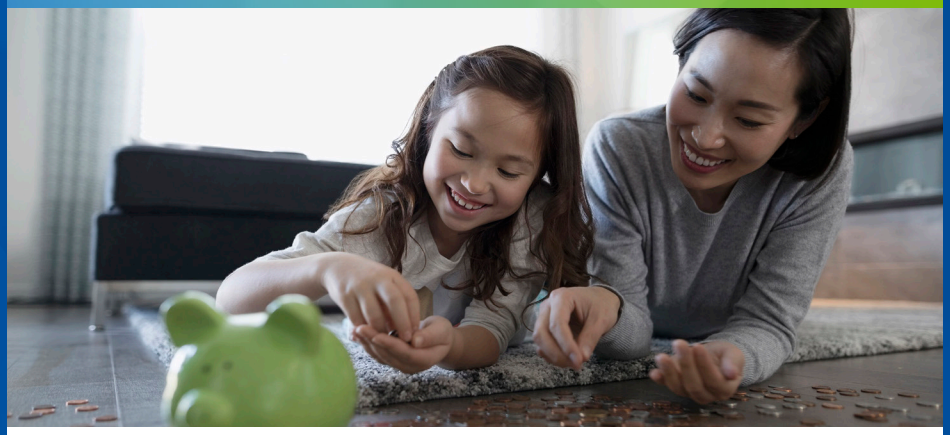
Elixir offers a PBM oversight report package delivered quarterly to the plan with PBM oversight metrics, determination trending and benchmark reports.

Automated steps and real-time request monitoring provides in-depth oversight

Initial coverage determinations must be completed within 24 hours for expedited requests and 72 hours for standard requests. Each episode of coverage (EOC) created in the automated prior authorization system (PAHub) has its own timer, which calculates the time remaining throughout the life of the EOC. Once reviewed and, if determined to be a favorable decision, the member's prior authorization (MPA) is created in the adjudication system in real time allowing the claim to process immediately.

With real-time access to view and monitor requests, plans can:

- Monitor current trends and volume in real time
- Decrease retroactive identification of untimely requests
- Review member requests at a time convenient to the plan
- Confirm appropriate clinical decision making and language is provided to the member
- Perform detailed oversight of coverage determination and redetermination functions



Pharmacy Audit and Fraud, Waste and Abuse

The effort to ensure validity and accuracy of pharmacy claims can be overwhelming and costly. With our claims investigation and recovery services, millions of dollars have been returned to plan sponsors.

Claims Investigations and Recoveries

Elixir detects, prevents, investigates and addresses potential instances of fraud, waste and abuse (FWA) and makes monetary recoveries on behalf of the health plan. Elixir has previously been recognized by the National Health Care Anti-fraud Association (NHCAA) for substantial contributions into the fraud database. Our approach includes:

- Detection analytics and data mining, for identification of outliers in pharmacy claims billing, generation of audits and investigative leads
- Pharmacy claims audits to address waste, verify accuracy of billed claims and pharmacy documentation
- Detailed investigations of pharmacies and members, utilizing interviews, wholesaler invoice reconciliations and other investigative techniques
- Suspension of offending pharmacies in the plan's network
- Monitoring of fraud alerts with active cooperation and referrals to federal, state, and local law enforcement and regulatory agencies
- Enhanced FWA review of pharmacies during credentialing and pre-credentialing invoice reconciliation audits

Elixir maintains an organizational membership with the NHCAA, allowing for access to multiple anti-fraud initiatives, education and training opportunities, as well as multiple tools and resources that increase the effectiveness of the Special Investigations Unit.

Elixir processes 100% of Part D claims through more than 40 proprietary algorithms and risk reports to identify high-risk claims and pharmacies for audits and investigations. In addition to proactive analytics, reports of potential FWA are received through our compliance hotline and other internal sources. Recovered overpayments identified through pharmacy audits are returned to the plan, minus any service charges as outlined in the agreement.

43

Fraud Cases Referred to Law Enforcement or Regulatory Agencies

51

PHARMACIES SUSPENDED
from the network due to FWA activities

58

PHARMACIES TERMINATED
due to FWA

80%

SUSPENDED PHARMACIES
identified through data mining activities

$18M

saved on behalf of clients through FWA activities

*Data for calendar year 2022

Pharmacy Credentialing

Before entering into a contract, pharmacies must go through formal credentialing. Our credentialing process includes analysis of active licensure, verification of absence from any government debarment, and compliance with accreditation requirements, state/federal regulations, and other acceptable industry standards.

Our pharmacy credentialing team uses a CMS-recognized credentialing process, which focuses on high fraud areas of the country,* as determined by the Health and Human Services Office of the Inspector General, and expanded by our Pharmacy Audit and Fraud, Waste and Abuse team.

**We apply stricter requirements for pharmacies in these areas that are applying to be included in our network.*

Network Compliance

Once a pharmacy enters our network, it is subject to ongoing compliance monitoring and auditing.

This monitoring and oversight of the pharmacy network includes:

- **Prompt payment of claims**
- **Troubleshooting and assisting prescriber in relation to data issues**
- **First tier, downstream and related entities (FDR) oversight and auditing of network pharmacies**
- **Ensuring sufficient pharmacy network access for members**
- **Support with CMS audit requests of pharmacy data**
- **Prescriber enrollment data and system applications**
- **Adequacy and integrity of provider directory files**
- **Application of appropriate state and federal prescriber and pharmacy preclusions, exclusions and sanctions, and the proper member notification for each**
- **Creation of plan-specific networks based on defined criteria**
- **Credentialing and re-credentialing**

For pharmacies that don't meet our ongoing compliance standards, Elixir sends notices and takes necessary action. Following this, plans receive monthly pharmacy network lists. All of our efforts contribute to the end goal, which is to deliver an adequate, accessible and compliant network for your members.

Crafting Solutions to Today's Pharmacy Benefits Challenges

ASK THE EXPERTS

Request an assessment of your current compliance approach

Get our perspective on your compliance questions

Receive information on our compliance roundtables and other online events

compliancedepartment@elixirsolutions.com

Learn about other strategies to improve plan performance and member outcomes

blog.elixirsolutions.com

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