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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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 patients receive the right care, at the right time, and keep patients' 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. EnvisionRx 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 patient 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 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 5 Star bonus payments are all consequences of noncompliance.

In 2017, CMS audited 36 plan sponsors, with almost half of them (47%) receiving enforcement actions as a result of cited conditions. Civil money penalties (CMPs) imposed totaled $2.9 million, with the highest CMP of nearly $1.4 million.1 Enforcement actions can cost plan sponsors millions in monetary fines, and in some cases, suspend their ability to enroll members and grow their business.

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 patients, 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 patients we care for every day.

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, EnvisionRx can share knowledge of the regulatory landscape from a clinical and pharmaceutical perspective, 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, EnvisionRx 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 visibly different 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.
WHEN IT COMES TO COMPLIANCE, FIVE THINGS YOU SHOULD EXPECT FROM YOUR PBM

1  Transparent Performance
   Protect your business and the member

EnvisionRx operates in a fully transparent 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 EnvisionRx, our auditing programs, investigation and recovery services help protect your revenue and control costs. With a focus on quality member care, EnvisionRx 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 to correction, reveal patterns of fraud, waste and abuse, and provide enforcement standards and quality controls that safeguard PHI.

4  Ongoing Insights
   Compliance team expertise

EnvisionRx acts as an extension of your compliance team, delivering insight and expertise to navigate the complex regulatory landscape and advance internal policies and practices to achieve compliance goals. We are continuously engaged in government audits across our books of business and take the opportunity to share audit insight that may impact other plan sponsors. EnvisionRx 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 attain and remain compliant with our core compliance suite of services and add enhanced services to custom 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.
Our professional compliance team is 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 EnvisionRx 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 EnvisionRx compliance officer participates in calls and meetings, both internal and external, and interprets CMS 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. EnvisionRx 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.

**An Accomplished Team of Experts**

Our subject matter experts provide a broad spectrum of experience to address any compliance challenge. Your EnvisionRx 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 Business Administration (MBA)
- Bachelor of Business Administration in Accounting (BBA)
- Certified Fraud Examiner (CFE)
- Certified in Health Care Compliance (CHC)
- Certified in Healthcare Privacy Compliance (CHPC)
- Certified in Risk Management Assurance (CRMA)
- Certified in IDEA Data Analytics
- Certified Information Systems Auditor (CISA)
- Certified Internal Auditor (CIA)
- Certified Information Privacy Professional (CIPP)
- Certified Pharmacy Technician (CPhT)
- Certified Public Accountant (CPA)
- Chartered Global Management Accountant (CGMA)
- HealthCare Information Security and Privacy Practitioner (HCISPP)
- Certified Information Systems Security Professional (CISSP)
- Certified Compliance and Ethics Professional (CCEP)

**COMPLIANCE ROUNDTABLES**

With an agenda of timely and relevant topics requested by our clients and business partners, our Compliance Roundtables are a collaborative peer forum on the regulatory environment.
ACHIEVING AN EFFECTIVE COMPLIANCE PROGRAM AS A TEAM

The Programs, Services and Tools You Need

EnvisionRx 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 OVERSIGHT

Simplifying the Complexity

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 compendium to help health plans understand all regulation implications and improve adherence. EnvisionRx helps plans make the most of these resources.
REGULATORY OVERSIGHT

In 2017, CMS released 543 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. EnvisionRx holds a weekly workgroup to review, analyze and operationalize guidance, from a plan sponsor’s perspective. EnvisionRx employs a multi-perspective approach, leveraging legal and compliance experts, as well as functional business unit subject matter experts. Through this detailed consideration to all possible impacts related to the PBM and plan sponsor activities and the member impact, compliance confidence is achieved.

Operational considerations include:
- Policies and procedures
- Monitoring and oversight practices
- Systems processes
- Crucial filing deadlines

In addition to weekly guidance reviews, more detailed analysis should include major CMS communications such as:
- CMS Annual Call Letter
- CMS Final Rule
- CMS Annual Part C and Part D Program Audit and Enforcement Report
- CMS Part D Readiness Checklist
INTERNAL OVERSIGHT 
AND ISSUE RESOLUTION

EnvisionRx 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.

In the instance that a deficiency is discovered, the business unit and compliance partner work in unison to remediate, develop a plan to correct and hardwire 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.

MARKETING MATERIALS

Plans are held accountable for following more than 130 pages of CMS Medicare Marketing Guidelines, updated annually. For the 2019 plan year, CMS proposed two significant changes—one that requires more robust compliance oversight to reduce risk of CMS enforcement actions and the other will make marketing activities easier. Permitting agents to disseminate more information at educational events and CMS’ clarification on what “misleading marketing materials” are, will inevitably increase oversight requirements to ensure compliance. On a positive note, CMS consolidating disclaimers into a one-time checklist within the Summary of Benefits, rather than multiple communications, will help streamline plan and PBM practices and prevent confusion with which disclaimer applies to a certain population.

EnvisionRx supplies health plans with all updated CMS model documents to assist in the creation of marketing 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 increase, compliance takes up more space in member communications. EnvisionRx works for and 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, EnvisionRx 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.
Protecting Health Information

One seemingly small Health Insurance Portability and Accountability Act (HIPAA) violation can have tremendously destructive consequences for businesses and plan sponsors, especially with new exposures like social media. EnvisionRx can help you protect member information, while also protecting your business from legal and monetary implications.

- Office for Civil Rights (OCR) received 477 reports of healthcare breaches affecting over 5.6 million people in 2017.
- Of the 477 reports, there were 10 reports that totaled $19.4 million in fines and penalties.
HIPAA PRIVACY

When it comes to privacy, plan sponsors are under greater scrutiny than ever before, tasking their compliance departments with the overwhelming responsibility of monitoring and ensuring compliance with several federal and state requirements, including HIPAA and the Health Information Technology for Economic and Clinical Health (HITECH) Act.

A core activity of the EnvisionRx privacy program is to provide assurance of compliance with privacy policies, regulations and laws. Our compliance team offers broad experience in these areas and has developed a variety of tools to help you stay compliant.

• Ensure appropriate business associate agreements are in place with subcontractors exposed to member information
• Provide personnel training and education
• Administer routine monitoring, oversight, and auditing
• Collaborate on cyber privacy, security practices and infrastructure
• Oversee operational systems to respond to allegations
• Perform detailed investigations and root cause analysis on privacy related issues
• Perform risk analysis on every privacy incident report
• Execute privacy incident response plan
• Lead and coordinate the Privacy Oversight Committee, a multi-disciplinary workgroup
• Maintain up-to-date knowledge of federal and state privacy laws and HIPAA regulations to ensure organizational compliance

Plan sponsors are required to develop and document policies and procedures, and ensure proper execution for practices related to the use, disclosure and access to PHI both electronically and in hardcopy form. EnvisionRx will consult with you on your HIPAA policies and processes. We will assess, update and improve your current plan policies and procedures. Training and education can be provided for all levels, including the board of directors, executive leadership, management and operations to increase HIPAA privacy awareness.

As the regulatory landscape around compliance and privacy continues to advance, U.S. healthcare organizations need to safeguard personal data more than ever. The European Union’s (EU) General Data Protection Regulation (GDPR), which became effective May 2018, is generally regarded as the most comprehensive privacy regulation in the world. Any business that markets, tracks or handles EU personal data must comply. In the U.S., similar efforts are also underway. California, for example, recently passed new privacy legislation that is the strongest in the country, and is modeled after GDPR.

While these disruptive regulations can seem daunting, a proactive approach to implementing cutting-edge privacy and security programs is the key. If an organization is already strongly HIPAA compliant and has good risk management operations, it will be well-positioned to successfully integrate these new regulatory frameworks. Through robust systems and compliance controls, EnvisionRx offers innovative solutions to tackle this new world of data management and protection.
INTERNAL AUDIT

Accuracy and Assurance

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

EnvisionRx 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 a 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.

DATA SECURITY

Security of your data is of the highest importance to us. To that end, EnvisionRx established a security governance program in which Privacy, Security and Internal Audit 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.

CLAIMS ADJUDICATION AND FINANCIAL ACCURACY AUDITS

On a semi-annual basis, EnvisionRx conducts a performance guarantee audit across the 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 claims adjudication and financial accuracy levels. To maintain a high degree of objectivity, the audits are conducted by our Internal Audit department.
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. 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 and CMS allows only three chances to get universes correct. There is a high risk of incurring fines and sanctions, both of which can hurt businesses.

Because EnvisionRx is in constant state of audit readiness, we provide quarterly universes of initial coverage determinations and redeterminations formatted in compliance with CMS’ audit protocols. If the plan is audited, EnvisionRx partners with the plan throughout the entire process, including corrective action plan development and validation audits, as well as live participation in the CMS audit.

EnvisionRx prepares and implements appropriate corrective actions if needed and takes necessary steps to reassure the plan and CMS that deficiencies are corrected.

EnvisionRx conducts mock audits following CMS audit protocols and timelines with ‘How To’ step-by-step audit processes and procedures. These mock audits are practice audits for the applicable functional areas of the PBM and compliance department to ensure EnvisionRx remains in a state of CMS audit readiness. Our Clinical Audit compliance team acts as the auditors and the functional area team participates as the audited party.

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

MEDICATION THERAPY MANAGEMENT (MTM)

To meet CMS requirements, plans must offer MTM to members with multiple chronic conditions and 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 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 and include MTM in the mock audits conducted by EnvisionRx.
CDAG continues to be scrutinized by CMS and is one of the leading sources of CMPs and fines to plans. With changes to CMS Program Audit Protocols, Annual Reporting Requirements, Technical Specifications, and the addition of the annual Timeliness Monitoring Project (TMP), plans struggle to stay in tune with CMS requirements.

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

- Quarterly universes in CMS’ table layout for standard audit Protocols for coverage determinations, redeterminations (appeals), and call logs
- Quarterly summary report on total coverage determinations and redeterminations along with approval and denial rates
- 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.

EnvisionRx provides 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
CDAG REPORTS

To meet CMS expectations for proper PBM oversight, health plans will automatically receive a number of easy-to-read, actionable reports.

QUARTERLY OVERSIGHT TRENDING REPORTS

- Coverage Determination Turnaround Time
- Coverage Determination Overview
- Direct Member Reimbursements (DMR)
- Grievances received by the PBM
- Appeals / Redeterminations
- Formulary Administration
- Prescription Volume
- FDA Recalls
- Vacation Overrides
- Medication Therapy Management (MTM)
- Prescription Drug Event (PDE)
- Rejected Claims
- Transition Claims
- Terminated Pharmacies
BENEFIT INTEGRITY

Fraud Waste and Abuse Detection

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

EnvisionRx detects, prevents, investigates and addresses potential instances of fraud, waste and abuse (FWA) and makes monetary recoveries on behalf of the health plan. EnvisionRx has even been recognized by CMS during a FWA training for its work fighting fraud, which resulted in several provider indictments. 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
- Member monitoring for drug seeking and doctor shopping, including prescriber notification and validation of pharmacy claims
- Detailed investigations of pharmacies, members and prescribers, 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

EnvisionRx 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.

OUR PHARMACY CLAIMS AUDIT RESULTS

- Millions of dollars returned to health plans
- Referrals to law enforcement and external agencies: 54
- Pharmacies suspended from network: 57

Source: EnvisionRx, 2017.
Once a pharmacy enters our network, it is subject to ongoing compliance monitoring and auditing.

This monitoring and oversight includes:

- Ensuring sufficient pharmacy network access for members
- First tier, downstream and related entities (FDR) oversight and auditing of network pharmacies
- Support with CMS audit requests of pharmacy data
- Prescriber enrollment data and system applications
- Application of appropriate state and federal prescriber and pharmacy exclusions and sanctions
- Pharmacy access oversight
- Creation of plan-specific networks based on defined criteria

For pharmacies that don’t meet our ongoing compliance standards, EnvisionRx sends notices and takes necessary action. Following this, plans receive monthly network lists of pharmacies added or removed from the network. All of our efforts contribute to the end goal, which is to deliver a compliant network and an accurate provider directory so you are assured of absolute compliance and an adequate network.
PHARMACY CREDENTIALING

Before entering into a contract, pharmacies must go through formal credentialing. We seamlessly integrate credentialing into the plan’s claims adjudication process with analysis of licensure, registration, authority to prescribe, enrollment, identifier and status of pharmacies, physicians, and authorized prescribers. In addition, pharmacies coming into our network are re-credentialed every three years to ensure continued suitability for network participation.

Our Healthcare Fraud Prevention and Enforcement Action Team (HEAT) 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 Network Compliance and Credentialing team.

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

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). EnvisionRx has established policies and procedures to ensure compliance as a first tier entity to the plan and provides downstream entity oversight. Subcontractors or vendors should be used sparingly, with robust monitoring and oversight practices in place.

EnvisionRx 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.

EnvisionRx 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.

EnvisionRx reviews the Health and Human Services (HHS) List of Excluded Individuals and Entities (LEIE), as well as 8 federal and 43 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 EnvisionRx. Those that pass our corporate integrity validations must attest in writing that they have an effective, active compliance program in place.

EnvisionRx assists in the creation of a complete 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.

PROGRAM EFFECTIVENESS

EnvisionRx was recognized at a Medicare Drug Integrity Contractor (MEDIC) conference in 2015 for the effectiveness of our FDR oversight program.
COMPLIANCE OVERSIGHT

HPMS Memoranda
CORE: Easy-to-read weekly update, analysis, and recommended action on recently released HPMS Memoranda.

Internal Oversight and Issue Resolution
CORE: Oversee plan sponsor-delegated functions to ensure potential issues are discovered.

Marketing Materials
CORE: Information on Medicare Marketing Guidelines and the submission process.

Member Communication
CORE: Consultation on compliant member communications, including call center compliance requirements.

PRIVACY OPERATIONS

HIPAA Privacy
CORE: Protect and safeguard member information, ensure appropriate business associate agreements are in place with subcontractors, personnel training and education, routine monitoring and auditing.
ENHANCED: Assess, update and improve current policies and procedures. Training for all organizational levels.

INTERNAL AUDIT

SOC Reports
CORE: Annual examination of internal procedures that impact financial reporting controls, resulting in a SOC 1, Type II report required by financial auditors.

Data Security
CORE: Security governance program to support the protection of member PHI and PII from a physical, technical and operational security standpoint.
**Claims Adjudication & Financial Accuracy Audits**

**CORE:** A performance guarantee audit across the book of business, designed to assess the financial and adjudication accuracy of member claims, including testing ingredient cost accuracy, dispensing fees, member copayments, eligibility, drug coverage and deductible application.

**CLINICAL AUDIT SERVICES**

**CMS Audits & Audit Preparedness**

**CORE:** Quarterly universes of initial coverage determinations, assistance with corrective action plans and validation audits (including annual data validation), and participation of EnvisionRx compliance experts on CMS calls.

**ENHANCED:** A mock audit following CMS audit protocols and timelines with audit processes and procedures, optional CMS onsite audit support and post mock audit to validate corrective action.

**MTM**

**CORE:** Interventions for potential drug therapy problems, comprehensive medical reviews and targeted medication reviews, with annual reporting provided quarterly.

**ENHANCED:** Monitor and validate the plan’s MTM compliance with Part D regulations and guidelines, including mock audits using MTM subject matter experts to prepare for audits.

**CDAG**

**CORE:** Real-time access to view and monitor requests and quarterly trending reports.

**ENHANCED:** PBM oversight report package delivered quarterly to the plan’s FTP site with PBM oversight metrics, determination trending and benchmark reports.

**BENEFIT INTEGRITY (FWA)**

**Claims Investigations and Recoveries**

**CORE:** Identify potential high-risk claims and pharmacies, with recoveries passed to the plan, and provide periodic reporting.

**ENHANCED:** For commercial plans, daily pre-pay claims review and audit services, including custom reports and onsite audits of pharmacies.

**NETWORK COMPLIANCE AND CREDENTIALING**

**Network Compliance**

**CORE:** Formal credentialing for pharmacies before serving as a network pharmacy.

**Pharmacy Credentialing**

**CORE:** Pharmacy identification and formal initial credentialing, including a monthly report of pharmacies added or removed from network participation. Determination and real-time analysis of licensure, registration, authority to prescribe, enrollment, identifier, and status of pharmacies, physicians, and authorized prescribers.

**ENHANCED:** Client-specific pharmacy networks based on defined criteria and oversight audits.

**FDR Entities**

**CORE:** Downstream entity compliance oversight through federal and state-specific databases, corporate integrity and compliance program validation checks, including annual audits and reporting. Annual audits of downstream entities provide reports that include corrective actions.

**ENHANCED:** Create CMS-compliant FDR oversight program with subject matter experts, tools and resources.
SEE WHAT A VISIBLY DIFFERENT APPROACH CAN DO FOR YOU

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

envisionrx.com/compliance-info

More Ways to Improve

Learn about other strategies to improve plan performance and patient outcomes

visiblydifferent.envisionrx.com

ABOUT ENVISIONRX  |  ENVISIONRX.COM

EnvisionRx is a Pharmacy Benefit Manager (PBM), providing affordable and effective prescription drug coverage for employers, unions and health plans. Using its proprietary EnvisionCare model, EnvisionRx optimizes all aspects of the pharmacy care experience to consistently achieve better patient and plan outcomes.