Pharmacy waste, fraud, and abuse in health care reform
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Objective: To describe the new Medicare and Medicaid waste, fraud, and abuse provisions of the Affordable Care Act (H.R. 3590) and Health Care and Education Affordability Reconciliation Act of 2010 (H.R. 4872), the preexisting law modified by H.R. 3590 and H.R. 4872, and applicable existing and proposed regulations.

Summary: Waste, fraud, and abuse are substantial threats to the efficiency of the health care system. To combat these activities, the Department of Health and Human Services and Centers for Medicare & Medicaid Services promulgate and enforce guidelines governing the proper assessment and billing for Medicare and Medicaid services. These guidelines have a number of provisions that can catch even well-intentioned providers off guard, resulting in substantial fines. H.R. 3590 and H.R. 4872 augment preexisting waste, fraud, and abuse laws and regulations. This article reviews the new waste, fraud, and abuse laws and regulations to apprise pharmacists of the substantial changes affecting their practice.

Conclusion: H.R. 3590 and H.R. 4872 modify screening requirements for providers; modify liability and penalties for the antikickback statute, federal False Claims Act, remuneration, and Stark Law; and create or extend auditing and management programs. Properly navigating these changes will be important in keeping pharmacies in compliance.

Keywords: Health care reform, Medicare, Medicaid, regulations, waste, fraud, abuse.

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During the previous 10 years, numerous settlements have occurred between the government and large health care providers, including pharmaceutical companies, pharmacies, and hospital chains, over fraud and false claims. In 2000, the Hospital Corporation of America, which was the largest hospital chain at that time, agreed to a settlement of more than $840 million in criminal and civil fees. In 2001, TAP Pharmaceuticals agreed to pay more than $675 million for fraudulent pricing and claims. In 2006, the Tenet Healthcare Corporation entered into a $900-million settlement regarding fraudulent billing and kickbacks, and in that same year, St. Barnabas Health Care System (the largest health care system in New Jersey) paid $265 million to resolve allegations that nine of its hospitals fraudulently increased charges to elderly patients to obtain enhanced Medicare reimbursement for outlier claims. In 2008, CVS Caremark agreed to pay $36.7 million to resolve its liability based on allegations that it improperly switched drugs that it billed to Medicaid programs in 23 states. These settlements were all eclipsed by the 2009 payment by Eli Lilly of $1.4 billion in civil and $515 million in criminal fines for off-label drug promotions, and Pfizer paid $2.3 billion to settle allegations of off-label drug promotion and other violations. These high settlement amounts show the prevalence of fraud and abuse in the system and the government’s increasing diligence when it comes to enforcing these laws.

In 2009, Medicare covered 45.5 million beneficiaries at a total cost of $486 billion; Medicaid had 51 million beneficiaries and cost the federal government $217 billion. The Centers for Medicare & Medicaid Services (CMS) estimated that improper payments for Medicare fee-for-service alone totaled $24.1 billion. Some have estimated that waste, fraud, and abuse cost as much as $100 billion a year. The Affordable Care Act (ACA) and the Health Care and Education Reconciliation Act signed into law by President Barack Obama in March 2010 promise to reduce health care expenditures by enacting stricter provisions against waste, fraud, and abuse in the system. The new legislation includes many antifraud and program integrity initiatives, including new transparency requirements, provider screening and enrollment requirements, amendments to federal antifraud tools, waste prevention that is specific to pharmacies, new ways to review postpayment claims, and increased penalties for offenders. With health care costs expected to continue to increase, the government has targeted providers and suppliers that intentionally defraud government programs and ones that unintentionally cause these programs to make improper payments.

The government will spend $290 million during the next 10 years to combat Medicare and Medicaid fraud and abuse. Most of the money will go to government agencies so that they can better monitor and combat waste, fraud, and abuse. On May 20, 2009, Department of Health and Human Services (HHS) Secretary Kathleen Sebelius and Attorney General Eric Holder announced the creation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) joint task force, which consists of staff from the Office of Inspector General (OIG) and Department of Justice. HEAT will use advanced data analysis techniques to identify potentially criminal activity among health care providers and to detect fraud schemes. It also will focus on new prevention techniques. In addition, CMS will contract with private companies to audit the federal and state health care programs; this will include Recovery Audit Contractors (RACs) that will audit providers for overpayments and Zone Program Integrity Auditors (ZPICs) that will monitor for fraud and abuse.

New screening requirements

New screening and enrollment requirements will affect all providers, including pharmacists who provide services to Medicare, Medicaid, and Children’s Health Insurance Programs. Before ACA was passed, no provider screenings occurred, although providers were required to disclose criminal records. The new screening requirements will include a licensure check, a criminal background check, fingerprinting, unscheduled and unannounced visits, database checks, and other appropriate screening. This provision also requires that providers seeking to enroll or reenroll must disclose any current or previous affiliations with any other provider or supplier that has collected debt or has been suspended or excluded from any federal health care program. New providers (i.e., providers who were not enrolled in any of the programs before March 23, 2010) will be subject to the new enrollment and screening requirements beginning March 2011. Providers who were enrolled before March 2010 will not be subject to the screenings until March 2012. Providers who are seeking to revalidate their enrollment...
must be screened if they revalidate after September 19, 2010. Last, no provider will be able to receive payment from any federal program after March 23, 2013, if he or she has not been screened.  

**Practice check**  
Which provider category does your organization fall into? If your organization is a “new provider,” is it ready to meet the new screening requirements by March 2011? If your organization was enrolled as a provider before March 23, 2010, will it be ready to meet the screening requirements by March 2012?

**False claims**  
The federal False Claims Act (FCA) originated during the Civil War to prevent people from selling faulty animals, guns, ammunition, and other provisions to the U.S. government. Fines could result if false claims were made about an item in order to obtain money from the government. Today, FCA is used by the government to recover improper or false payments made by government health care programs to providers or suppliers. A person is liable under FCA when that person “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.”  

In pharmacy, FCA violations usually occur because of inappropriate billing practices such as up-coding, billing for nonexistent prescriptions, billing for brand-name drugs when generics are dispensed, billing prescriptions that were never picked up, and other forms of fraudulent behavior directed at Medicare or Medicaid. These are considered false claims because the pharmacist is intentionally making a claim for reimbursement for services that were not rendered or were rendered in a manner different from what was claimed.

**Practice check**  
Does your organization teach its personnel to spot fraudulent behavior directed at Medicare or Medicaid?

FCA itself was not changed by the health care reform (HCR) legislation, but civil monetary penalties were increased for false claims made to federal health care programs. The fine for making a false claim to a health care program increased from $10,000 to $50,000 plus three times the amount of the claim for each false statement or record. In addition, a fine of $15,000 per day results if the provider or supplier does not allow access to HHS for audits or other investigations. An overpayment made by a federal health care program also will be considered an “obligation” under FCA if it is not paid within 60 days from when the overpayment was identified. Whether the overpayment will be considered a false claim under FCA is unclear, but identifying an overpayment as an obligation under FCA indicates that liability could exist under the act. These provisions are meant to compel providers and suppliers to comply with all rules and regulations attached to government health care program reimbursement and to be prompt when an overpayment has been identified.

**Antikickback**  
The Medicare antikickback statute (AKS) underwent two major changes after ACA was passed. First passed in 1972, AKS prohibits anyone from “knowingly and willfully soliciting or receiving any remuneration directly or indirectly under a federal healthcare program” or “knowingly and willfully offering or paying any remuneration directly or indirectly under a federal healthcare program.” AKS essentially prohibits the exchange of remuneration for patient referrals or for goods and services that may be covered in part or wholly by a government-funded plan. Over the years, the Social Security Act continued to be amended, transforming AKS from a misdemeanor to a felony. Currently, violating the provision can result in criminal prosecution, including a maximum $25,000 fine and 5 years in prison. Civil penalties for violating AKS include a $50,000 fine and a “three strikes” provision mandating permanent exclusion from federal health care programs for providers guilty of three health care–related offenses.

Traditionally, prosecutors have enforced AKS by focusing on transactions between a person or entity making a referral and the recipient of the referral. Prosecutors then would gather evidence that would indicate a higher amount of referrals flowing from one entity to another and evidence of above-market payments between the two. In 1985, the Third Circuit ruled that even if payments were made to compensate the provider for professional services, if one purpose of the payments is to induce referrals—even if it is not the primary purpose—then a violation of AKS has occurred. Following that ruling, AKS became a broad tool that the government could use to prosecute health care providers for a range of different practices. In one case, a manager of a nursing home in Michigan contracted with pharmacies that supplied his patients (who were primarily Medicaid patients) with supplies and services in exchange for alcoholic beverages. In a high-profile case, TAP Pharmaceuticals settled with the government and paid more than $875 million in criminal and civil fines for providing free samples of drugs to physicians and then encouraging them to bill Medicare for the medications. The cases have ranged from clearly criminal behavior to providers waiving copayments and deductibles for beneficiaries.

AKS has a much broader reach than other fraud and abuse statutes. It no longer implicates only payments for referrals made under Medicaid or Medicare. Any payment for ordering, providing, leasing, furnishing, recommending, or arranging for the provision of any service, item, or good payable by a federal program is suspect under AKS. Almost any type of economic benefit that can flow to anyone capable of increasing business with government program beneficiaries can be scrutinized, and all parties to an arrangement are liable to both civil and criminal prosecution. Because of this, many health care providers have expressed concern that they could be prosecuted for engaging in regular business practices. This led the government to create safe-harbor regulations specifying various types of practices that are immune to prosecution under AKS. These safe harbors cover many different types of business.
practices, but they all come with detailed conditions. For instance, the personal services safe harbor requires seven conditions to be met before a payment made by a principal to an agent will be considered a legal remuneration. These standards include the following: (1) that the agreement is in writing and is signed by both parties, (2) that the agreement covers all services that the agent will provide to the principals, (3) that the agreement specifies whether the services will provided on a part-time or full-time basis and the exact schedule of the activities, (4) that the agreement is for more than a year, (5) that the aggregate compensation paid is set in advance and at fair market value and does not take into account the volume or value of any referrals generated, (6) that the services performed do not violate federal or state law, and (7) that the aggregate services contracted for do not exceed those that are reasonably necessary to accomplish the business purpose of the services. The personal services safe harbor is one of the least complicated safe-harbor provisions, but in other industries, a principal–agent relationship would not be required for any of these conditions (Table 1).

HCR introduced two important changes to AKS that dramatically increased the potential liability of providers. For several years, AKS has been used in conjunction with FCA to increase liability for violating the statute. When a violation of AKS is prosecuted along with FCA, each violation can cost the defendant up to $50,000 plus three times the amount of the damages sustained by the government. ACA changed the law so that any violation of AKS constitutes a false claim under FCA. As a result of that change, prosecutors no longer have to prove or establish a connection between a false claim and a violation of AKS.

In addition to making an AKS violation the equivalent of a false claim, ACA also changed the intent requirement. The Ninth Circuit had established that to violate AKS, the defendant needed to know the statute’s proscriptions and intend to violate them. This requirement is difficult to prove: therefore, the government has not used AKS as a basis for prosecution as frequently as other fraud and abuse statutes. Under ACA, the intent requirement has been reduced to “a person need not have actual knowledge of this section or specific intent to commit a violation of this section.” This change could result in substantial criminal and civil exposure for providers even if they did not intend to violate the statute. Whether this occurs will become clearer as defendants are tried under the new law in court.

Both of the changes made by the HCR legislation greatly increase liability for providers who violate AKS. All claims made to Medicare and Medicaid arising from a violation of AKS will constitute false claims and carry the additional costs. With the increased liability, pharmacists and other providers will have to be more diligent when engaging in a transaction or other arrangement with other providers or suppliers.

### Remuneration

The new exceptions made to the definition of “remuneration” could be advantageous for pharmacies. Federal law prohibits providers from offering patients covered by any government health care program certain inducements (e.g., discounts, other remunerations) if the provider “knows or should know” that the inducement “is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier...

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**Table 1. Summary of business practices exempt from AKS by safe harbors**

<table>
<thead>
<tr>
<th>Safe Harbor</th>
<th>Description</th>
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<tbody>
<tr>
<td>Payments that qualify as a return on investment</td>
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<tr>
<td>Payments for the rental of space</td>
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<tr>
<td>Payments for the rental of equipment</td>
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<tr>
<td>Personal services and management contracts</td>
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<tr>
<td>Payments relating to the sale of a practice</td>
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<tr>
<td>Qualifying payments for referral services</td>
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<tr>
<td>Warranties provided by a manufacturer or supplier to a buyer</td>
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<tr>
<td>Certain qualifying discounts</td>
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<tr>
<td>Payments by employers to bona fide employees</td>
<td></td>
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<tr>
<td>Payments to qualifying group purchasing organizations</td>
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<tr>
<td>Waiver of beneficiary coinsurance and deductible amounts</td>
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<tr>
<td>Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans</td>
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<tr>
<td>Price reductions offered to health plans</td>
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<tr>
<td>Payments for practitioner recruitment</td>
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<tr>
<td>Obstetrical malpractice insurance subsidies</td>
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<tr>
<td>Investments in group practices</td>
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<tr>
<td>Cooperative hospital services organizations</td>
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<tr>
<td>Payments resulting from a return on investments for ambulatory surgical centers</td>
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<tr>
<td>Certain qualifying referral arrangements for specialty services</td>
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<tr>
<td>Price reductions offered to eligible managed care organizations</td>
<td></td>
</tr>
<tr>
<td>Price reductions offered by contractors with substantial financial risk to managed care organizations</td>
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<tr>
<td>Gifts or transfer of drugs or medical supplies to an ambulance provider (or first responder) to replenish comparable materials used in the transport of a patient</td>
<td></td>
</tr>
<tr>
<td>Qualifying transfers of goods, items, services, donations, or loans to health centers</td>
<td></td>
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<tr>
<td>Nonmonetary remuneration of electronic prescribing items and services</td>
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<tr>
<td>Nonmonetary remuneration of electronic health records items and services</td>
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</tbody>
</table>

Abbreviation used: AKS, antikickback statute.

This table is only designed to be a summary of potentially available exemptions to AKS. Each safe harbor has its own specific criteria that must be met for the business practice to be eligible, and the regulations should be consulted before relying on the safe harbor.
any item or service for which payment may be made, in whole or in part, under a government program; in short, remunerations are treated like kickbacks. The blanket prohibition against remuneration prevented pharmacies from giving out coupons or other types of rewards to patients covered by any government program. In addition, any violation of this law was treated like a false claim, and the provider could be liable for $10,000 for each claim plus three times the amount of each claim.

Remuneration has been defined as anything having value but offered for free or for a price different than its fair market value. The only exception allowed, until 2002, was the waiver of copays and deductibles under certain conditions: (1) if the waiver is not offered as part of any advertisement or solicitation, (2) if the person does not routinely waive coinsurance or deductible amounts, and (3) if the person waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need or fails to collect coinsurance or deductible amounts after making reasonable collection efforts. In 2002, OIG created a new exception to the law that allowed providers to “offer inexpensive gifts or services, that have the retail value of no more than $10 individually and no more than $50 in the aggregate annually per patient.” This law was difficult for pharmacies and other providers to work with because tracking the $50 annual limit was difficult. In 2007, OIG allowed a rewards program offered by warehouse clubs that operated community pharmacies. This program offered customers rewards of less than 5% of what they had spent at the warehouses, including spending on prescription drugs, OIG decided not to impose sanctions because the program presented a “minimal risk” of abuse and the rewards were not “tied” to drug purchases.

The HCR legislation added four new exceptions to the remuneration statute. The first exception allows any remuneration that promotes access to care and poses a low risk of harm to patients and the government health programs. The second exception allows providers to offer or transfer items or services for free or less than market value if the items or services consist of coupons, rebates, or other rewards. These coupons or rebates must be transferred on equal terms and to the general public, and they cannot be tied to the provision of other items or services reimbursed by a government health program. The third exception allows providers to offer items or services for free or for less than market value if they are not offered as part of any advertisement, if they are not tied to the provision of other services reimbursed by a government health program, if a reasonable connection exists between the items and services and the medical care of the patient, and if those items or services are provided only after a good faith determination that the patient is in financial need occurs. The final exception allows Medicare Part C and D sponsors to offer to waive the copayment for the first refill of a covered Part D drug if it is a generic.

OIG has not interpreted these new exceptions; therefore, pharmacies should wait before designing new rewards programs. Section F, which allows “any other remuneration which promotes access to care and poses a low risk of harm to patients and federal health care programs,” is very broad; thus, guidance is needed before providers use that statute to offer rewards. In addition, how “retailer” will be defined in section C is unclear; there is no guarantee that it will include pharmacies. No date has been set for when OIG or HHS will have to begin writing regulations for these new provisions; therefore, providers should consult their attorneys before offering coupons or rebates to customers.

Stark Law

The Stark Law is very similar to AKS in that it prohibits providers from benefiting from making patient referrals. Stark prohibits a physician from making a referral for designated health services to an entity that the physician or a physician’s immediate family member has a financial relationship with; these are known as self-referrals. A financial relationship can mean two things. The first meaning is an ownership or investment interest through equity, debt, or any financial interest other than publicly traded stocks and bonds. Exceptions also exist for rural providers that meet certain conditions. In the second meaning, compensation arrangements that involve a remuneration between a physician and a designated health services entity are prohibited, and this rule has a huge amount of exceptions. Remuneration, as defined in the Stark Law, means any payment or other benefit made directly, indirectly, in cash, or in kind. The exceptions relate to amounts forgiven for certain tests or billing errors, certain specimen collections and related items and supplies, and certain payments by an insurer or self-insured plans and their subcontractors to settle claims.

The Stark Law got its name from Representative Fortney “Pete” Stark (D-CA), who pushed for the passage of the Omnibus Budget Reconciliation Act of 1989. Known as Stark I, the law prohibited physicians from referring patients to clinical laboratories with which the physician had a financial relationship. Stark II, passed in 1993, added 11 more designated health services and introduced the first exceptions to the law. Currently, there are 12 designated health services: (1) clinical laboratory services; (2) physical therapy services; (3) occupational therapy services; (4) radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; (5) radiation therapy services and supplies; (6) durable medical equipment and supplies; (7) parenteral and enteral nutrients, equipment, and supplies; (8) prosthetics, orthotics, and prosthetic devices and supplies; (9) home health services; (10) outpatient prescription drugs; (11) inpatient and outpatient hospital services; and (12) outpatient speech/language pathology services. The Stark III rules were
Improper payments made for services that do not meet Medicare’s medical necessity criteria, (2) payments made for services that were incorrectly coded, (3) proper documentation not submitted by providers upon request, (4) claims based on outdated fee schedules, and (5) duplicate claims submitted.

In 2008, Medicare processed more than 1.2 billion claims that were submitted by more than 1 million providers. HHS estimated that between April 2008 and March 2009, $24.1 billion dollars (or 7.8% of claims) were spent on improper claims for Medicare Parts A and B. As a partial solution to this problem, CMS devised a plan to use private companies (i.e., RACs) to review postpayment claims data and identify improper payments.

In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), which authorized CMS to complete a demonstration project to determine whether RACs could be used effectively to track improper payments made by Medicare. In March 2005, CMS contracted with three private RACs for the demonstration. California, New York, and Florida were chosen for the initial part of the demonstration because they are the three largest states in terms of Medicare use. Each RAC was assigned a single state and sent approximately 400 million claims to audit. In December 2006, the Tax Relief and Health Care Act was passed, making RACs permanent and authorizing the expansion of the program to all states by January 2010.

In 2007, the demonstration program expanded to include Massachusetts, Arizona, and South Carolina. Today, four RACs are operating in all 50 states, with each RAC contractor having its own region.

CMS published the results of the first RAC demonstration in March 2008. In New York, Florida, and California, the RACs managed to recover $1.03 billion in improper payments; 96% of payments were overpayments that were recovered from providers. Of those claims, 14% were appealed by providers that were audited, and only 4.6% of the claims were overturned on appeal. During that same period, regular Medicare claims processors managed to recover only $13 million in overpayments. RACs work off of contingency fees based on what they recover, with these fees ranging from 9% to 12.5%; therefore, the government does not spend money to recoup overpayments.

RACs use two different methods to conduct claims reviews. The first type is an automated review; RACs use proprietary software to analyze claims for overpayments, incorrect codes, and duplicate claims. Automated reviews for making coverage and coding determinations are limited to situations in which a Medicare policy or coding guideline is available and confirmation exists that the service is not covered or that a coding error is present. The second type is a complex review; these reviews are done by licensed physicians and other providers to determine whether the treatment was medically necessary or if that particular service was covered by Medicare. Complex reviews are used in situations in which a service likely was not covered and no Medicare guidelines are available.

RACs are a powerful tool to combat overpayments made
by government health programs, but because they are not meant to target entities that are engaged in fraud and abuse of the system, certain limitations are imposed on them. RACs can review only claims that have already been paid; they do not review or even have access to prepayment claims data. RACs may use only “targeted reviews.” RACs use data analysis techniques to compare historical data before they can target a particular provider, and they cannot target a claim solely because of its high dollar value. Auditors only have a 3-year “look-back” period; therefore, they cannot examine claims that were filed more than 3 years before the review. They also are limited to 10 medical records every 45 days from solo practitioners. RACs may request only 10% of the average monthly Medicare claims, with a maximum of 200 every 45 days, from hospitals. The purpose of these limitations is to ensure that RAC audits do not have too much of a negative impact on patient care.

ACA calls for states to establish programs to contract with RACs by the end of 2010 to begin reviewing improper Medicaid claims. In addition, Medicare will expand its RAC program to cover Part D prescription plans and Medicare Advantage plans starting in 2011. Special rules relating to Parts C and D will be established requiring that RACs (1) ensure that each Medicare Advantage plan under Part C has an established antifraud plan, (2) ensure that each prescription drug plan under Part D has an antifraud plan, (3) examine claims for reinsurance payments to determine whether prescription drug plans submitting such claims incurred costs in excess of the allowable reinsurance costs permitted, and (4) review estimates submitted by prescription drug plans with respect to the enrollment of high-cost beneficiaries and compare these estimates with the number of beneficiaries enrolled by the plans.

Because RACs are used more heavily throughout the entire health care system, pharmacists should be aware of the potential that these entities have for disrupting a practice. With the expansion to Medicaid and Medicare Part D, RACs can turn their attention to pharmacies and audit the Medicare and Medicaid claims submitted by the pharmacy. With the 3-year look-back period, pharmacies that have billed government health care programs improperly, even by accident, will be liable and will have to return all overpayments. Even if each overpayment is small, 3 years of claims can add up to a large amount of money.

### Zone Program Integrity Contractors

Zone Program Integrity Contractors (ZPICs) were established in 2009 by CMS to audit the integrity of all Medicare-related claims. CMS consolidated the work of Program Safeguard Contractors and Medicare Drug Integrity Contractors into seven ZPIC zones. Unlike RACs, which target billing mistakes, ZPICs will be in charge of auditing providers for fraud and abuse. ZPICs will be paid by CMS; their fee will not be contingent on what they find.

ZPICs will use data analysis to detect abnormalities between providers and national trends. They will monitor for patient abuse and harm, multistate fraud, high dollar overpayments, and large fraud patterns. ZPIC audits also may be triggered by referrals from other contractors or beneficiary complaints. After an investigation has started, ZPICs will be authorized to conduct audits, interview beneficiaries and providers, start administrative sanctions (e.g., payment suspensions, Medicare exclusion), and refer providers to law enforcement agencies or recover overpayments. ZPICs will be able to monitor pre- and postpayment claims that have been filed within 3 years of the audit.

Every pharmacy, and especially should take steps to prepare for a ZPIC audit, especially large pharmacies. Providers may take the following steps in preparing for an audit: (1) ensure that the fraud and abuse compliance program is active and functioning correctly; (2) designate a point person to handle ZPIC audit requests; (3) develop a multidisciplinary committee that has representation across all departments, so that the entire organization can assist in developing and implementing procedures in case of an audit; and (4) create an intake and tracking system to monitor audit deadlines. If a proper fraud and abuse compliance program is in place and billing is being done correctly, then an audit by either a RAC or ZPIC will most likely not occur. However, the possibility always exists that an audit can occur; therefore, mechanisms should be in place so that everything runs smoothly.

### Medication therapy management and nursing home medication dispensing

One way in which ACA plans to combat waste and help Medicare beneficiaries with drug use is through medication therapy management (MTM). MMA recognized the value of MTM by requiring Part D sponsors to design and implement MTM plans for certain Medicare beneficiaries. CMS made changes to the requirements for the MTM plans in 2010, and these changes have been codified in ACA along with a grant program to further encourage pharmacists to use MTM.

Federal law defines MTM as “a program of drug therapy management that may be furnished by a pharmacist and that is designed to assure that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions.” The plans should include basic provisions that enhance patient understanding of medications to promote appropriate use, increase patient adherence to prescription medication regimens, and help pharmacists detect adverse drug events and patterns of overuse and addiction. Federal regulations require that MTM plans include (1) screening for potential problems resulting from therapeutic duplication, (2) age-/gender-related contradictions, (3) over- and underuse, (4) drug–drug interactions, (5) incorrect drug dosage or duration, (6) drug–allergy contraindications, and (7) clinical abuse/
misuse of prescription drugs. MTM plans must be developed by licensed pharmacists and physicians, and they must allow patients to opt out.

Medicare patients must meet three requirements to qualify for a Medicare MTM program. The patient must have at least two chronic diseases to be targeted, but plans cannot require that a patient have more than three diseases to qualify. Sponsors must target at least four of the following chronic diseases:

- Hypertension
- Heart failure
- Diabetes
- Dyslipidemia
- Respiratory disease
- Bone disease (e.g., arthritis)
- Mental health disease

Patients must be taking at least two drugs to qualify but must be targeted if they are taking eight or more drugs. The final requirement is the likelihood that the patient will have at least four prescribed drugs, take any high-risk medication, have two or more chronic diseases, and have recently undergone a transition of care. The patient must take at least four prescribed drugs, take any high-risk medication, have two or more chronic diseases, and have recently undergone a transition of care. This new program was supposed to start on May 1, 2010; however, no news regarding the grants has surfaced, and the funding remains unclear.

ACA also introduced new requirements that will go into effect on March 23, 2012. First, pharmacists or other qualified MTM providers will be required to perform an annual comprehensive medication review furnished person to person or using telehealth technologies: this will include a review of the patient’s medications and may result in a recommended medication action plan or other actions in consultation with the patient and input from the prescriber, as well as a written summary of the results. Second, pharmacists or other qualified MTM providers will be required to perform follow-up interventions as warranted. Third, the plan sponsor will assess, at least on a quarterly basis, the medication use of patients who are at risk but are not enrolled in the MTM plan. Fourth, the plan sponsor will have a process to automatically enroll targeted beneficiaries and permit beneficiaries to opt out of enrollment.

These new provisions are intended to increase the number of Medicare patients in MTM plans and enhance the quality of MTM plans to increase patient safety. Another hope is that the new MTM requirements will reduce spending by helping to eliminate medication overuse and prevent drug interactions that cause health problems in patients.

To further reduce waste and potential fraud, ACA will require Plan D sponsors to develop uniform dispensing techniques for pharmacies within nursing homes. On January 1, 2012, nursing homes will no longer be allowed to dispense 30-day fills of prescription drugs covered by Medicare. CMS will have to develop new regulations for this particular provision, but the statute states that the monthly dose will be reduced to a weekly, daily, or automated dose.

**Conclusion**

The government is more focused than ever when it comes to weeding out waste, fraud, and abuse in Medicare and Medicaid. Congress is hoping that part of the funding for HCR can come from stopping fraudulent activity that costs billions of dollars, as well as recouping overpayments that cost the government tens of billions of dollars each year. These hopes are pinned on the enhanced penalties, private audits, and increased funding for enforcement. The laws will put a greater burden on providers to monitor their billing practices and business relationships and will require providers to be more responsible for fixing errors and disclosing their relationships.

Regulations that will apply to these laws have not been written, and some of them will not be created for at least a few years. Because these important details are not yet available, providers will have to be even more conservative when it comes to their practices. Violating these laws can cost huge amounts of money in penalties and potentially shut down even the largest providers. Honesty and integrity, combined with awareness of the laws, will go a long way in protecting providers from these great liabilities.

**References**


10. Id.


12. Id. at § 1395cc(j)(1)(B).

13. Id. at § 1395cc(j)(5)(A).

14. Id. at § 1395cc(j)(2)(D).


17. Id.

18. 42 U.S.C. § 1320a-7b(g)(1)–(2).

19. Id.


22. 42 U.S.C. § 1320a-7b(g)(1)–(2).

23. H.R. 3590 § 6402(a).

24. H.R. 3590 § 6402(a), (8), (9), (12).

25. H.R. 3590 § 6402(a).


52. Id. at § 1320a-7a(a)(5).
54. 42 U.S.C. § 1320a-7a(a)(12).
55. Id. at § 1320a-7a(ii)(6).
56. Id. at § 1320a-7a(ii)(6)(A).
57. 67 Fed. Reg. at 55855.
59. Id.
60. 42 U.S.C. § 1320a-7a(ii)(6)(F).
61. Id. at § 1320a-7a(ii)(6)(G).
62. Id. at § 1320a-7a(ii)(6)(H).
63. Id. at § 1320a-7a(ii)(6)(I).
64. Id. at § 1320a-7a(ii)(6)(F).
65. Id. at § 1320a-7a(ii)(6)(G).
68. Id. at § 1395nn(a)(1).
69. Id. at § 1395nn(a)(2)(A), (c)(1), and (d).
70. Id. at § 1395nn(a)(2)(B) and (h)(1).
71. Id. at § 1395nn(h)(1)(C).
73. Id.
74. Id.
75. 42 U.S.C. § 1395nn(h)(6).
76. Id.
77. Id. at §1395nn(g)(3),(4).
78. Id.
83. Id.
84. H.R. 3590 § 6409.
85. Id. at § 6409(a)(1).
86. Id. at § 6402(b).
88. Id. at 1.
89. Id. at 9.
93. Id. at 11.
94. Id.
95. Id.
98. Id. at 11.
100. Id. at 2.
101. Id. at 20.
102. Id.
108. Id.
109. Id. at 9.
110. Id.


115. Id. at § 1395ddd(h)(9).


117. Id.


120. Id.

121. Id. at 10.


123. Id. at 5.


127. Id. at § 1395w-104(c)(2)(B).


129. Id. at 423.153(d)(3).

130. Id. at 423.153(d)(2)(i).


135. HR 3590 § 3503(a) and (c).

136. Id.

137. Id. § 3503(d).


139. Id. at § 1395w-104(c)(3).

140. Id.

141. Id.
CPE exam

Instructions: The assessment test for this activity must be taken online; please see “CPE information” below for further instructions. There is only one correct answer to each question. This CPE activity will be available at www.pharmacist.com no later than February 28, 2011.

1. The Affordable Care Act (ACA) and the Health Care and Education Reconciliation Act target waste, fraud, and abuse by:
   a. Increasing penalties for various fraudulent activities directed at Medicare and Medicaid.
   b. Providing avenues for tracking, review, and auditing claims.
   c. Enhanced screening of providers.
   d. All of the above alternatives are correct.

2. Which of the following statements regarding Medicare, Medicaid, and the Children’s Health Insurance Program providers enrolled before March 23, 2010, is correct?
   a. They will have to meet the new screening requirements by March 2012.
   b. They will have to meet the new screening requirements by March 2011.
   c. They are fully exempt from the new screening requirements.
   d. They are partially exempt from the new screening requirements.

3. Which of the following is not an example of a false claim under the federal False Claims Act (FCA)?
   a. Coding for a more expensive medical device than what was actually dispensed to the patient.
   b. Billing Medicare for a prescription order that was canceled by the patient.
   c. Referring a patient to another health care provider in whom the referring physician has a financial interest.
   d. None of the above alternatives is correct; all are examples of false claims.

4. Under the revised FCA penalty provisions, a false claim can result in a penalty of:
   a. A civil fine of up to $50,000.
   b. A civil fine of up to three times the amount involved in the false claim.
   c. Both alternatives a and b are correct.
   d. Neither alternative a nor b is correct.

5. Overpayments by a federal health care program to a provider:
   a. Must be returned in full within 30 days of the discovery of the overpayment.
   b. Will be considered an obligation under FCA unless returned in full within 60 days of the discovery of the overpayment.
   c. May be kept by the provider even though the provider discovers that the payment was in fact an overpayment because the mistake was no fault of their own.
   d. Are automatically considered a false claim if not returned in full within 60 days of the discovery of the overpayment.

6. Penalties for an antikickback statute (AKS) violation include:
   a. Up to three times the amount “kicked back” to the provider for the illegal referral.
   b. A criminal fine up to $25,000 and/or 5 years in prison, a $50,000 civil penalty, and a permanent exclusion from federal health care programs after “three strikes.”
   c. Suspension from participating in federal health care programs.
   d. All of the above alternatives are correct.

7. For a business transaction to fall into an AKS safe harbor:
   a. The business transaction must meet each of the specific requirements for each safe harbor.
   b. The business transaction need be constructed only so as to roughly conform to the purpose of each safe harbor.
   c. The business transaction must be approved in writing by the appropriate government agency (e.g., Centers for Medicare & Medicaid Services [CMS]) before implementing the practice.
   d. A report detailing the business transaction must be submitted to the appropriate government agency (e.g., CMS) within 30 days after implementation.

8. Which of the following statements best describes the relationship between AKS and FCA after the health care reform legislation passed?
   a. AKS and FCA control two distinct areas of business practices and are not related to one another.
   b. An AKS violation cannot occur if an FCA violation occurs first.
   c. An AKS violation also constitutes an FCA violation.
   d. A prosecutor must show a causal connection between the false claim and the kickback to prove that a provider violated FCA and AKS.
9. Under the reforms enacted by ACA, what is the intent that must be shown to prove that a provider is guilty of an AKS violation?
   a. An intent to violate or actual knowledge that the action constitutes a violation of AKS
   b. Actual or constructive knowledge that the action constitutes a violation of AKS
   c. Direct premeditated intent to violate AKS
   d. A person need not have actual knowledge of this section or specific intent to commit a violation of AKS.

10. The strict prohibition against remuneration to patients such as Medicare Part D enrollees has been relaxed because:
   a. Little risk to patients exists and some remuneration can promote access to care.
   b. The prohibition was found to be unconstitutional.
   c. Remuneration encourages competition for Medicare and Medicaid patients.
   d. All of the above alternatives are correct.

11. Under the reforms enacted by ACA, a provider may offer or transfer items or services for free or less than market value in which of the following scenarios?
   a. If the items or services consist of coupons, rebates, or other rewards
   b. If the coupons or rebates are transferred on equal terms and to the general public
   c. The offer or transfer cannot be tied to the provision of other items or services reimbursed by a government health program.
   d. All of the above alternatives are correct.

12. A physician who refers a Medicare beneficiary to a national DMEPOS (durable medical equipment, prosthetics, orthotics and supply) supplier in which he/she holds a small percentage of stock (<0.001% of shares) is:
   a. Violating FCA.
   b. Violating the Stark Law.
   c. Violating AKS.
   d. Likely not violating any law.

13. For someone to be violating the Stark Law, that person:
   a. Must directly intend to violate the Stark Law.
   b. Must have actual knowledge that the action they are taking is a violation of the Stark Law.
   c. Is liable if they know or should know that the transaction violates the Stark Law by making a self-referral.
   d. Need not have intent but must have actual knowledge that the referral they are making is a violation of the Stark Law.

14. Recovery Audit Contractors (RACs) operate to reduce billing mistakes by:
   a. Examining every Medicare and Medicaid billing by a provider in real time before payment to root out any improper claims.
   b. Conducting automated audits to check for improper coding for certain items and complex audits to see whether procedures are medically necessary or covered.
   c. Inspecting all applicable billing records of a randomly selected provider for the previous 5 years.
   d. Requiring providers to submit all applicable billing records to an information clearinghouse for inspection.

15. The information that RACs can obtain from providers is limited to:
   a. Records up to 5 years old with no restriction as to quantity or timing.
   b. Records up to 5 years old with restrictions as to quantity and timing based on the type of provider being audited.
   c. Records up to 5 years old with no restriction as to quantity or timing.
   d. Records up to 3 years old with restrictions as to quantity and timing based on the type of provider being audited.

16. With respect to RACs, which of the following statements is correct?
   a. Pharmacies should prepare for the expansion of RAC audits to include Medicare and Medicaid billing by pharmacies.
   b. Pharmacies should not be concerned because the expansion of RAC auditing is unlikely to cover Medicare Part D.
   c. Pharmacies should be prepared to provide any billing information up to 7 years old to RAC auditors.
   d. All of the above alternatives are correct.

17. Zone Program Integrity Contractors (ZPICs) differ from RACs in which of the following ways?
   a. ZPICs collect a contingency fee based on the amount of improper billing they are able to recover from providers.
   b. ZPIC investigations are triggered by regional data analysis to spot trends that suggest fraudulent activity or can be tipped by provider or beneficiary complaints.
   c. ZPICs can only audit records during an investigation.
   d. ZPICs can only seek to recover overpayments if the investigation reveals improper billing practices.
18. Which of the following practices likely will not help prepare a pharmacy to respond to a ZPIC investigation?
   a. Ensuring that the fraud and abuse compliance program is active and functioning correctly
   b. Keeping records at separate individual sites instead of at a central recordkeeping location
   c. Creating an intake and tracking system to monitor audit deadlines
   d. Designating a point person to handle ZPIC audit requests

19. A medication therapy management (MTM) plan developed by pharmacists alone is improper because:
   a. The development of an MTM plan must include a patient advisory group.
   b. The development of an MTM plan must include input from CMS.
   c. The development of an MTM plan must be between physicians and pharmacists.
   d. The development of an MTM plan must be among physicians, lawmakers, and pharmacists.

20. An MTM plan that provides for pharmacists performing a comprehensive annual medication review, provides for pharmacists performing follow-up interventions as required, provides for plan sponsors performing a quarterly assessment of at-risk but unenrolled patients, and allows plan sponsors to automatically enroll target patients with patients retaining the ability to opt out is:
   a. In compliance with ACA reforms to MTM services and should reduce waste and prevent complications resulting from drug complications.
   b. Will greatly reduce the number of patients enrolled in MTM services.
   c. Will allow the government to reduce prescription drug benefits to Medicare beneficiaries.
   d. Will increase spending related to prescription drug benefits to eligible Medicare beneficiaries.

CPE information
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