Health Care Law

One Year Later

THE IMPACT OF HEALTH CARE REFORM



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The Patient Protection and Affordable Care Act (PPACA) expands Recovery Audit Contractor activities to Medicare Parts C and D and Medicaid.

PPACA further requires formal compliance plans for all Medicare providers; skilled nursing facilities are the first providers required to comply.

False Claims Act liability was clarified under PPACA; a provider has an affirmative duty to return an overpayment to the government.

The Patient Protection and Affordable Care Act (PPACA),¹ better known as the health reform bill, has shifted health care program integrity initiatives away from the "pay and chase" model used in previous years and refocused efforts on prevention and detection of health care fraud, waste, and abuse, with an emphasis on audits of providers' Medicare billings. Therefore, attorneys representing health care provider clients who submit claims to Medicare or Medicaid should be aware of how PPACA changes the audit and compliance landscape and know how to identify issues that could affect their clients' practices.

Specifically, PPACA is poised to increase both the scope and breadth of current audit activities with the expansion of the Recovery Audit Contractors (RAC) program into Medicare Parts C (Medicare Advantage Plan) and D (prescription drug coverage) and Medicaid. The RAC program involves relatively new federal contractors who audit Medicare providers. Attorneys who counsel providers and suppliers should also be aware of increased cooperation and data sharing among federal agencies, the potential for increased liability in connection with identified overpayments, and implementation of mandatory compliance programs for all providers and suppliers.

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Pre-PPACA Audit Landscape

Before the enactment of PPACA, audit activity originated from an array of sources including RACs, Medicare Administrative Contractors (MACs), Zone Program Integrity Contractors (ZPICs), and Medicaid Integrity Contractors (MICs). PPACA mainly impacted the RAC program.

Medicare Audits

Recovery Audit Contractors

Perhaps the most publicized auditors are RACs, who are paid a certain percentage based on the amount of overpayments they collect from providers. This pay structure makes RACs a type of "bounty hunter" for the federal government.

The RAC program began as a "demonstration" program in 2005 and, based on its success, Congress passed legislation in 2006² to establish the permanent RAC program that is now effective in all 50 states.³ The country is divided into four RAC regions, with one contractor assigned to each region.

RACs are permitted to conduct two types of reviews: automated or complex. An automated review does not involve a human review of medical records and may be used only when the RAC is certain that a service is not covered or incorrectly coded or a written Medicare guideline applicable to the service exists (such as when a service is incorrectly coded or billed twice). A complex review requires a human review of the medical records. If the medical necessity of a billed procedure is at issue, the RAC is required to have a registered nurse or therapist make the determination. A provider may request the credentials of the individual making the determination.

In identifying improper payments, RACs are also required to comply with reopening regulations.⁷ Specifically, the RAC must have and document good cause to reopen a claim more than one year from its initial determination.⁸ However, a recent United States District Court decision found that providers have little recourse when a RAC does not abide by the reopening regulations.⁹

As discussed in more detail below, PPACA mandates expansion of the RAC program to Medicare Parts C and D as well as Medicaid.

Medicare Administrative Contractors, Program Safeguard Contractors, and Zone Program Integrity Contractors

MACs, the entities that handle claims processing and administration, also frequently audit providers through the Medical Review program, which is geared toward reducing claim error rates by addressing billing errors involving coverage and coding. ¹⁰ The MACs first identify potential problems through data analysis and then conduct probe audits of select providers. If the percentage of claims containing errors is sufficiently high, contractors may subject providers to additional post-payment review, pre-payment review, or suspension of payments. ¹¹

Providers may also be subject to audits by Program Safeguard Contractors (PSCs) or ZPICs. The letter sent to the provider will normally indicate what type of contractor performed the audit. This information may be useful to the provider's counsel when researching the guidelines applicable to the contractor's claim review. PSCs, now transitioning into ZPICs,¹² are responsible for implementing Medicare's Benefit Integrity Program, which involves the identification of suspected fraud.¹³ These contractors may receive referrals from other contractors or conduct their own data analysis to identify potential fraud.¹⁴

Medicaid Audits

Historically, the responsibility for Medicaid fraud enforcement fell predominately on the states, but the Deficit Reduction Act of 2005 created federal oversight through the Medicaid Integrity Program (MIP). The aim of the MIP is to prevent, identify, and recover inappropriate Medicaid payments. The MIP also supports the program integrity efforts of state Medicaid agencies through a combination of oversight and technical assistance.¹⁵

In contrast to RACs, the Centers for Medicare & Medicaid Services (CMS) established a five-year audit "look back" period for MICs to identify overpayments. Also unlike RACs, MICs are not paid on a contingency-fee basis and are not responsible for collecting overpayments from providers. Instead, the federal government collects its share of identified overpayments directly from the state. The state is responsible for recovering the overpayments from the providers. ¹⁶ As with the RAC program, payments



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to providers may be suspended once overpayments are identified.¹⁷ All provider appeals are handled through the state appeals process pursuant to state law.¹⁸

Impact of Health Care Reform on Audits

Expansion of the RAC Program

While PPACA mandated expansion of the RAC program to Medicare Advantage Plan (Part C) and Medicare prescription drug coverage (Part D) and to Medicaid by December 31, 2010, CMS is currently in the process of developing a RAC program applicable to Medicare Parts C and D, and recently released a proposed rule addressing implementation of the Medicaid RACs.

Medicare Parts C and D

In contrast to traditional fee-for-service Medicare, Medicare Advantage organizations are paid monthly on a capitated basis, i.e., Medicare pays a set amount per patient each month to a private insurer and the insurer is required to provide at least as much coverage as traditional Medicare. Similarly, Part D plan sponsors are paid a direct subsidy for each eligible, enrolled beneficiary based on the plan's approved, adjusted bid.

In light of the different payment structures in place, CMS recently solicited comments on the most efficient way to utilize RAC functions in connection with reimbursement to Part C and Part D plans.²¹ CMS sought comments on the methods for RACs to use in identifying overpayments and underpayments in the Part C and Part D plans, the qualifications necessary for a contractor to appropriately review claims in these programs, establishment of an oversight entity for approval of issues for review, methods for resolving underpayments, and options for how RACs will be paid for identified underpayments.²² The solicitation also contemplates allowing Part C and Part D plans to use RACs internally to identify overpayments in their operations. In this capacity, the RAC would review claims submitted to the Medicare Advantage organization by health care providers serving the plan's enrollees and would then be paid on a contingency-fee basis by that organization.²³

The payment structure in place for Medicare Advantage organizations also impacts overpayment recoupment options. Under the fee-for-service RAC program, once overpayments are identified by

RACs, the MAC recoups them from the provider's current Medicare billings. In contrast, Part C plans are paid on a capitated basis, making the plan directly at risk for overpayments made to its providers. CMS also sought comments on recoupment models that may be applicable in the Part C setting.²⁴

In addition to identifying overpayments and underpayments, RACs are also required to ensure that Medicare Advantage and prescription drug plans have effective anti-fraud procedures in place.²⁵ Providers and their counsel can expect to see the impact of the expansion to Parts C and D as the program develops.

Medicaid

CMS recently released a proposed rule that provides guidance to states regarding the establishment of the Medicaid RAC program. ²⁶ It is important to note that the Medicaid RAC program is *in addition to*, not in place of, the Medicaid Integrity Program and state Medicaid integrity initiatives. Because of these multiple programs, Medicaid providers, including physicians and other health care providers, are faced with a greater likelihood of audits in the year ahead.

Medicaid RACs are tasked with reviewing post-payment claims data for improper overpayments and underpayments. Pursuant to PPACA, states were required to establish their Medicaid RAC programs by December 31, 2010, using the state plan amendment process.²⁷ While states were originally required to have their programs up and running by April 1, 2011, a recent CMS bulletin indicated that states will not be required to implement their Medicaid RAC programs until the final rule is issued later this year.²⁸

Like the Medicare RACs, Medicaid RACs will be paid on a contingency-fee basis. The RAC contingency is "taken off the top" of the overpayment amount, i.e., states will be required to report overpayments to CMS based on the net amount remaining after the requisite contingency fee is paid to the Medicaid RAC.²⁹ States are required to refund the federal share of the overpayment regardless of whether they are actually able to recover the overpayments from the provider.³⁰ This requirement could be a burden for states in which collecting identified overpayments from providers proves difficult.

Applying the lessons learned in the Medicare RAC demonstration project, the proposed rule requires Medicaid RACs to employ trained medical professionals to review provider claims.³¹ States



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The federal government is authorized to

are also required to have an adequate process to handle appeals from adverse audit decisions made by the Medicaid RACs.³² As long as a state's existing administrative appeals process—such as one used to handle MIC or Medicaid audit appeals—can accommodate Medicaid RAC appeals, CMS is not requiring states to adopt a new administrative review process.

Retaining Identified Overpayments

In addition to expanding the RAC program, PPACA also creates new risks for false claims liability when auditors identify overpayments. Specifically, PPACA clarifies that a provider has an affirmative duty to return an overpayment it has received and notify the appropriate entity (such as CMS, the Office of the Inspector General (OIG), or the carrier) regarding the reason for the overpayment.³³ This must occur no more than 60 days from "the date on which the overpayment was identified" or "the date any corresponding cost report is due, if applicable."³⁴ However, PPACA does not define when an overpayment is "identified" for purposes of reporting and returning.

Retention of an overpayment beyond the deadline for reporting and returning also creates the possibility of liability under the False Claims Act (FCA),³⁵ especially in light of recent changes to the FCA resulting from the Fraud Enforcement and Recovery Act of 2009 (FERA).³⁶ Specifically, FERA makes it a violation of the FCA to "knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the Government."³⁷

These changes raise many issues for providers in the audit process. One consideration is whether a negative appeal determination creates an identified overpayment that must be paid back in 60 days. Further, questions may arise regarding a provider's potential liability when the provider cannot afford to pay back an overpayment.

The OIG has yet to clarify many issues surrounding this legislation, including when overpayment return obligations are triggered during the audit process. Although the appeals process will likely protect against CMS finding a "known" obligation, there is some risk that the OIG could prosecute individuals and entities who are not timely in repaying overpayments under the FCA, especially if there is no good-faith basis for appeal, e.g., no documentation to support the services provided.

FCA liability is significant. Possible repercussions include civil monetary penalties of up to \$11,000 for each item or service, an assessment of three times the amount claimed for each item or service, and payment of the government's costs and attorney fees. Additionally, providers who violate the FCA may be excluded from participating in federal and state health care programs. Moreover, pursuant to additional PPACA revisions, the mere failure to repay an overpayment (even without FCA liability) can lead to exclusion from the Medicaid and Medicare programs. On the medicaid and Medicare programs.

Data Sharing

PPACA places a priority on data sharing and matching between federal programs to enhance effectiveness and interagency cooperation in detecting fraud and abuse. The government has introwithhold funds from state Medicaid programs if those states do not report data to the Medicaid Statistical Information System.

duced federal data-sharing programs in the past, but most have been aimed at keeping consumers informed of cost or quality.⁴¹ Section 6402 of PPACA establishes an Integrated Data Repository for CMS that includes claims and payment data from Medicare and Medicaid along with health programs administered by the Department of Veterans Affairs, Department of Defense, Social Security Insurance, and the Indian Health Service.⁴² PPACA further requires the U.S. Department of Health and Human Services (HHS) secretary to enter into data-sharing agreements with commissioners and secretaries of various agencies⁴³ and requires the respective agencies to share and match data in the system of records for purposes of identifying fraud, waste, and abuse.⁴⁴ Importantly, the federal government is authorized to withhold funds from state Medicaid programs if those states do not report data to the Medicaid Statistical Information System.

Mandatory Compliance Programs

PPACA mandates that all health care providers and suppliers of medical equipment adopt compliance plans as a condition of enrollment in Medicare.⁴⁵ The HHS secretary is charged with drafting the "core elements" of a compliance plan for each industry sector, which then must be implemented by any provider or supplier wishing to participate in Medicare.⁴⁶ The HHS secretary is responsible for setting a timeline to roll out the new core elements for each provider-specific category and then establishing a second timeline for providers and suppliers to adopt compliance programs.⁴⁷

While the HHS secretary has discretion to implement compliance regulations for most provider types, PPACA requires very specific timelines and guidelines for skilled nursing facilities (SNFs). The SNF compliance plans will serve as a model for the rest of the health care industries.

The law requires each SNF to have a compliance program "effective in preventing and detecting criminal, civil, and administrative violations" of the Medicare laws⁴⁸ in place by March 2013. By March 2012, the HHS secretary is required to establish regulations to guide SNFs in creating their own compliance programs, which can include a model program.⁴⁹ The regulations must take into account that SNFs of different sizes should be treated differently; that is, larger organizations should be required to have more formal programs than smaller ones.⁵⁰ The required components of each SNF program must include five core elements to prevent, detect, and appropriately address fraud.⁵¹ In light of these requirements, it is important for SNFs and all health care providers and suppliers to prepare to implement the core elements of the compliance program provided for their industry sectors.

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Conclusion

While PPACA's provisions on expanded health care access and federally mandated individual coverage were the main focus of media and public attention before passage, the law's attention to expanding mechanisms to fight fraud and abuse may be of more immediate concern to providers and suppliers participating in federally funded health care programs. Providers must be more alert than ever to the possibility of the government's auditing or otherwise investigating their practices.



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FOOTNOTES

- 1. PL 111-148, 124 Stat 119 (2010).
- 2. See 42 USC 1395ddd.
- 3. Id.
- 4. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, J-1 RAC SOW-Amendment 1, Statement of Work for the Recovery Audit Contractor Program, at 17 https://www.cms.gov/RAC/downloads/Final%20RAC%20SOW.pdf [hereinafter SOW]. All websites cited in this article were accessed May 14, 2011.
- 5. Id. at 18.
- 6. Id. at 19.
- 7. See 42 CFR 405.980; see also SOW n 4 supra, at 6.
- 8. 42 CFR 405.980.
- See Palomar Medical Center v Sebelius, unpublished opinion of the United States District Court for the Southern District of California, issued July 28, 2010 (Docket Nos. 19, 24, 37) 2010 WL 2985837 at 2-3; 2010 US Dist LEXIS 76093, at 8-9.
- See U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Medicare Program Integrity Manual, Pub 100-08, ch 1, §1.3 (2009) (on file with author).

- 11. See id. at ch 3.
- 12. Id. at ch 4, §4.1.
- 13. Id. at ch 4, §4.2.
- 14. Id. at ch 4, §4.2.1-2.
- U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Comprehensive Medicaid Integrity Plan of the Medicaid Integrity Program, FYS 2009–2013 (July 2009) http://www.cms.hhs.gov/DeficitReductionAct/Downloads/CMIP2009-2013.pdf
- Medicaid Integrity Program; Eligible Entity and Contracting Requirements for the Medicaid Integrity Audit Program, 73 Fed Reg 55765 through 55768 (September 26, 2008).
- 17. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Comprehensive Medicaid Integrity Plan of the Medicaid Integrity Program, FYS 2006–2010, at 15 [July 2006] https://www.cms.gov/DeficitReductionAct/Downloads/CMIP2006.pdf.
- 18. lc
- 19. 42 CFR 422.304.
- 20. 42 CFR 423.329.
- Medicare Program: Solicitation of Comments Regarding Development of a Recovery Audit Contractor Program for the Medicare Part C and D Programs, 75 Fed Reg 81278, 81280 (December 27, 2010).
- 22. ld.
- 23. Id.
- 24. ld.
- 25. PL 111-148, 124 Stat 119 §6411(b) (2010).
- Medicaid Program; Recovery Audit Contractors, 75 Fed Reg 69037, 69045 (November 10, 2010).
- 27. PL 111-148, 124 Stat 119 §6411(a) (2010).
- 28. Medicaid Program; Recovery Audit Contractors, 75 Fed Reg 69037, 69045 (November 10, 2010); see also Letter from Peter Budetti, MD, JD, Deputy Administrator & Director, Center for Program Integrity, and Cindy Mann, Deputy Administrator & Director, Center for Medicaid, CHIP and Survey & Certification, to State Medicaid Directors re: Recovery Audit Contractors (RACs) for Medicaid (October 1, 2010) http://www.hms.com/docs/webinar_docs/02/CMS_Medicaid_RAC_Guidance_10_1_10.pdf; see also Letter from Budetti & Mann re: Clarification of CMS Expectations for State Implementation of Medicaid Recovery Audit Contractor (RACs) programs (February 1, 2011) https://www.cms.gov/MedicaidIntegrityProgram/Downloads/6411racdelay.pdf
- 29. Budetti & Mann, Clarification, n 28 supra.
- 30. 42 CFR 433.312.
- Medicaid Program; Recovery Audit Contractors, 75 Fed Reg 69037, 69045 (November 10, 2010).
- 32. ld.
- 33. PL 111-148, 124 Stat 119 §6402(d) (2010).
- 34. Id.
- 35. 31 USC 3729 et seq.
- 36. Fraud Enforcement and Recovery Act of 2009, PL 111-21, 123 Stat 1617 (2009).
- 37. 31 USC 3729(a)(1)(G).
- 38. 31 USC 3729(a)(1) and (a)(3).
- 39. 42 USC 1320a-7(b)(7).
- 40. PL 111-148, 124 Stat 119 §6502 (2010).
- See, e.g., Fletcher, Bush Signs Order on Health Care: Agencies Required to Provide Data on Cost, Quality of Services, Washington Post, August 23, 2006 http://www.washingtonpost.com/wp-dyn/content/article/2006/08/22/AR2006082200330.html>.
- 42. PL 111-148, 124 Stat 119 §6402(a) (2010).
- 43. Id.
- 44. Id. §6402(a)(1)(B).
- 45. Id. §6102(a)(8)(A).
- 46. Id. §6012(a)(8)(B).
- 47. Id. §6012(a)(8)(C).
- 48. Id. §6102.
- **49**. Id.
- **50**. Id.
- 51. Id. Specifically, each SNF must (1) have procedures that are "reasonably capable" of preventing criminal, civil, and administrative violations; (2) have identified individuals within an organization to oversee the compliance program, who must have sufficient resources; (3) ensure that organizations use due care to avoid delegating authority to individuals who "ha[ve] a propensity to engage in criminal, civil, and administrative violations"; (4) ensure that organizations communicate program standards to all employees and agents, take reasonable steps to achieve compliance with program standards, and consistently enforce the standards; and (5) ensure that organizations will respond appropriately if an offense is detected.