Compliance in an Era of Federal and State Health Reform: Fitting a Square Peg in a Round Hole

By Tracy E. Miller

Aligned with health reform policies adopted by the Affordable Care Act, state governments have relied upon the purchasing power of Medicaid programs to advance health system transformation. To date, eight states have implemented the Delivery System Reform Incentive Payment Program (DSRIP) in some form as the primary vehicle to attain Medicaid and health system reform. The federal Centers for Medicare and Medicaid Services (CMS) has indicated that it regards New York State's program as the leading model.[1]

With $8.25 billion in funds from the federal and state governments, New York State's DSRIP program is staggering in the magnitude of its size, ambitions to reengineer the delivery system, and the speed at which it aims to achieve system redesign. The twenty-five organizations chosen as the leads (PPS Leads) for Performing Provider Systems (PPSs) in the State have been expected over the past two years to: (i) design integrated delivery systems comprised of hundreds, and in some cases thousands, of providers and social service organizations; (ii) develop detailed plans for six to 11 projects that engage providers in their PPS; (iii) build the infrastructure and analytic capacity for population health management; (iv) create and manage a representative governance structure; (v) enter into contracts covering the five-year term of DSRIP that span financial, governance, clinical, data sharing, and compliance arrangements; and (vi) determine how best to coordinate care and share data across the continuum of care.[2] PPSs will be paid in the first DSRIP years primarily based on pay-for-reporting, with payments transitioning over the five-year DSRIP term to payments for performance, weighted toward reducing preventable hospital admissions and use by 25%. Over the life of DSRIP, PPSs are also expected to transition to value-based payment arrangements with Medicaid managed care organizations, which will depend in turn on performance incentives that align payments to participating organizations with PPS incentives.

Embedded in the challenge of building the infrastructure and managing the operations of an emerging delivery system comprised of hundreds of disparate providers and social service agencies is the requirement that each PPS establish and operate an effective compliance program in accordance with New York State law, and address the myriad compliance issues that arise. Those issues are posed by Medicaid payments for the novel projects and services PPSs must deliver, the flow of those funds to participating organizations, and the fraud and abuse issues that arise in arrangements that, by design and intention due to explicit DSRIP goals, seek to change the referral patterns of patients among providers, effecting a shift from the inpatient to outpatient setting to reduce preventable hospital admissions and use.

Notably, PPSs and participating providers in DSRIP must tackle these compliance challenges without the benefit of the waivers as provided by federal agencies for the Medicare Shared Savings Program (Shared Savings Program) for accountable care organizations (ACOs). Specifically, ACOs in the Shared Savings Program operate with waivers from CMS and the United States Department of Health and Human Services (HHS), Office of Medicaid Inspector General, with respect to the application of the Stark Law, the Anti-Kickback Law (AKS) and the Civil Monetary Penalties Law (CMP) for the innovative payment arrangements that the Shared Savings Program seeks to foster.[3] In addition, the Internal Revenue Service provided guidance that applies to the disbursement and use of funds by participating exempt organizations. The Federal Trade Commission and the Department of Justice issued joint guidance related to anti-trust compliance, another major area of compliance that PPSs must address.[4]

Building a Compliance Program Across the Continuum

PPSs have by and large proceeded with two distinct corporate models; some PPSs formed unincorporated governance structures within hospitals or hospital systems, with a PPS governing body comprised of representatives from participating providers overseen by the board of the hospital or system. Other PPSs comprised of multiple hospital systems or other providers formed a new corporation (Newco) to govern the PPS. At this time, the PPSs are almost evenly split between these two models. For PPSs that formed Newcos, their first compliance challenge was to build a compliance program from the ground up that satisfies the requirements set by New York State regulations and the New York State Office of Medicaid Inspector General (OMIG), including hiring a compliance officer shortly after incorporating when most had no employment infrastructure or policies.[5] Hospital-based PPSs could rely on their existing compliance infrastructure, but had to determine how that would be revised to encompass hundreds of participating entities for DSRIP activities.

OMIG provided webinars and a guidance statement for PPS Leads regarding compliance.[6] The guidance

statement, issued first in April 2015 and then revised in September 2015 (Guidance Statement), advised PPS Leads that they must implement the required eight compliance program elements as applicable to PPS activities.[7] Significantly, OMIG underscored that while compliance programs by PPS Leads must cover issues posed by DSRIP, PPS Leads have no responsibility for overseeing or managing the compliance programs of participating providers in their own operations and services. This principle should run throughout PPS compliance programs and policies; training, reporting, monitoring, and activity to address compliance concerns should focus exclusively on issues posed by PPS operations, PPS projects, and DSRIP activities. This dividing line is critical to both PPS Leads and to participating providers; PPS Leads are not positioned to nor should they want to assume compliance oversight for hundreds of providers. For their part, participating providers and social service organizations will want to maintain their autonomy and the attorney–client privilege as they address internal compliance matters.

With respect to training, OMIG advised that PPS Leads are responsible for compliance training and education for all affected employees, governing body members, and executives throughout the PPS.[8] PPS Leads are not required to provide training directly; they can offer materials or webinars, but must track that training has occurred. For PPS Leads and participating providers, it will be important to determine who should be trained, rather than require blanket training that will not be relevant to workforce members who are not directly involved in a DSRIP project. OMIG advised that the obligation to participate in the PPS compliance program should be reflected in a contractual agreement; the primary agreements between participating organizations and PPS Leads (Participation Agreements) generally include this obligation.

OMIG guidance has stressed that PPS Leads will be responsible for any false data or statements that serve as the basis for a Medicaid payment, which may be deemed fraud and subject to repayment.[9] For this reason, many of the Participation Agreements spell out the obligation of organizations to assure the accuracy of data they submit related to performance and other areas that will be the basis for payment. In a webinar on February 26, 2015, devoted to DSRIP, OMIG asserted as well that PPS Leads would be held responsible for tracking the expenditure of funds by participating providers.[10] In the face of substantial objections to this oversight role by PPS Leads, the OMIG Guidance Statement clarified that PPS Leads are not responsible for how participating providers use DSRIP funds, but must have adequate processes to track performance, with the caveat that if performance falls short, it may trigger the need for an inquiry by the PPS Lead.

To the extent that PPS Leads must track performance in order to report on each DSRIP project to receive payment, OMIG's revised Guidance Statement does not impose a substantial additional responsibility on PPS Leads. At the same time, performance in achieving PPS project goals, such as integrating primary and behavioral health care and reducing preventable use of the emergency room by mental health and substance abuse patients, may fall short for a wide array of reasons entirely unrelated to how funds were expended. Yet, if OMIG demands an inquiry, it will inevitably turn, at least in part, on the use of Medicaid funds. The OMIG Guidance Statement, however, does implicitly give PPS Leads the leeway to require participating organizations to track the expenditure of funds and maintain records in the event of an inquiry, rather than requiring ongoing reports about fund expenditures and proactively overseeing the expenditures.

If an overpayment of Medicaid funds occurs, OMIG and the New York State Department of Health (NYSDOH) have advised that NYSDOH will initiate a process to recoup the funds from the PPS Lead by deducting the payments from future performance payments to the PPS Lead.[11] PPS Leads are in this regard accountable for the actions of participating organizations for the array of conduct that could lead to an overpayment, including submission of false data, reliance on an excluded individual, and mismanagement of Medicaid funds.

Avoiding Overpayments

DSRIP seeks to extend and accelerate activities already under way in federal and state health reform initiatives: care coordination and care management, expansion of primary care and patient-centered medical homes, and patient education and engagement. Yet, as suggested by Medicaid principles and expressly stated by NYSDOH, PPS Leads cannot pay participating providers for activities already paid for in whole or in part by Medicaid or Medicare. The same logic would apply to avoid the waste of public funds to activities paid for by other payers. While seemly simple, this requirement is complex in practice as PPS Leads seek ways to incentivize and support activities already covered in whole or in part by other sources of funds. One solution, especially for payment for activities such as care management, is to fund additional activities explicitly identified in project agreements with providers that are necessary for project implementation. Such activities might include data collection and reporting, improved information technology connectivity, outreach to other providers or to Medicaid beneficiaries not already engaged in care management, or in the case of physician practices that have already achieved patient-centered medical home status, payment to attain the next level of accreditation.

PPS Leads that serve regions that overlap with another PPS must also assure that participating organizations are not paid twice for services they provide. For many projects, health care providers and social service agencies are paid based on the number of Medicaid beneficiaries to whom they deliver a service, such as the Patient Engagement Project, which entails administering an interview instrument called the patient activation measure (PAM) to beneficiaries. In order to assure that participating organizations are not paid by another PPS for providing the instrument to the same Medicaid beneficiary, and that PPS Leads do not include the same beneficiaries when reporting to DOH for payment purposes, PPS Leads must coordinate with one another, requiring them to share personally identifiable data for thousands of Medicaid beneficiaries.

Applying the Fraud and Abuse Laws to Health System Transformation

Federal and state fraud and abuse laws apply to the activities of PPS Leads in disbursing DSRIP funds and designing and managing projects. The fraud and abuse laws also apply to the arrangements between participating organizations to carry out PPS projects. The applicable laws include the federal and state Stark Law, federal and state anti-kickback laws (AKS) and the Civil Monetary Penalties Law.[12] In contrast to PPSs in which the PPS Lead is a hospital or hospital system, PPS Leads that are Newcos do not deliver health care services, and do not bill Medicare or Medicaid as a provider. Compliance with the fraud and abuse laws is therefore less demanding for Newco PPS Leads than for hospital PPS Leads, but still poses complex issues in the flow of funds for DSRIP projects and performance incentives.

The Stark Law prohibits physicians from referring patients to an entity for designated health services (DHS), such as physical therapy or clinical laboratory tests, if the physician or an immediate family member has a direct or indirect financial relationship (compensation, investment, or ownership interest) with that entity, unless an exception applies.[13] Since Newco PPS Leads do not deliver or bill Medicare or Medicaid for DHS, they do not fall within the definition of "entity" under the Stark Law. Funds provided by Newco PPS Leads to physicians do not establish a direct financial relationship within the meaning of the Stark Law. Nor will the funds create an "indirect" financial relationship under the Stark Law as long as Newco PPS Leads do not pay physicians for project participation based on the volume or value of services that physicians refer to hospitals and other entities that bill for DHS.[14]

Application of the Anti-Kickback Law (AKS) is also distinct for Newco PPS Leads than for providers that bill Medicare or Medicaid for services. The AKS bars remuneration of any kind, directly or indirectly, to induce or in exchange for the referral of patients for goods or services paid for, in whole or in part, by a federal or state health care program. Newco PPS Leads do not deliver goods or services billed to Medicaid and Medicare, nor do participating health care providers in each PPS "refer" patients to Newco PPS Leads within the meaning of the AKS. However, participating providers refer patients to other providers in the PPS, and the referral of patients, if successful in meeting DSRIP performance metrics, such as reduced hospital admissions and use, will lead to higher payments for the PPS and for participating organizations. Fund flow models and performance metrics within PPSs operated by Newco PPS Leads must still be assessed and structured for AKS compliance.

PPS Leads that operate within the existing corporate structure of a hospital are "entities" within the meaning of the Stark Law. Physicians may refer patients to the hospital for services that are DHS, requiring that the funds provided by the PPS fit a Stark Law exception.[15] Hospital-led PPSs also disburse DSRIP funds to providers across the continuum of care for DSRIP implementation and performance, including physicians, nursing homes and FQHCs, all of which may refer patients to the hospital. The AKS therefore applies in a more conventional way to the payments by hospital-led PPSs, in contrast to payments by Newco PPS Leads, with implications for both the PPS Leads and participating organizations—the AKS prohibition and associated civil and criminal penalties apply equally to entities that offer and those that receive remuneration to induce or in exchange for referrals.

Conduct that falls within a safe harbor delineated by the AKS has the advantage of a presumption that the conduct does not violate the AKS; conduct outside of a safe harbor may still comply with the AKS, but is not presumed to do so. The personal services and management contract safe harbor as well as other AKS safe harbors, like many exceptions to the Stark Law, require that compensation be set in advance and be at fair market value (FMV). FMV is a challenging benchmark for PPS payments related to network and project development activities. For example, the initial tasks for many DSRIP projects entail outreach to other providers, entering into affiliation agreements, and implementing care protocols. Moreover, in order to succeed, PPS Leads must align payments to participating providers with the incentive payments they receive from the State, relying on performance-based payments that often cannot be set in advance, although the methodology for performance can be specified in advance as part of fund flow plans and project metrics. Other payments, such as the payments that PPS Leads will make to hospitals for lost revenue in

accordance with DSRIP, fall entirely outside the framework contemplated by the fraud and abuse laws.

For all PPS Leads, AKS compliance is complicated by the fact that the goals for certain DSRIP projects, and the overarching goal of reducing preventable hospital admissions and use by 25%, create a tension with the AKS. By seeking a significant shift in patient volume from the inpatient to outpatient settings, DSRIP and other health reform initiatives seek to change patient referral patterns and incentivize referral practices. For example, the DSRIP Emergency Department (ED) Care Triage Project (Project 2.b.iii) funds PPSs to engage participating EDs to reduce preventable ED admissions and refer patients to primary care practices, when medically appropriate. The most direct metric for project performance, and corresponding payment structure, would be payment to EDs based on the number of patients they refer to a primary care practice. Indeed, that is precisely the metric used by DOH for purposes of determining patient engagement for performance payments to PPSs related to speed and scale of project implementation.[16] Yet, EDs refer patients to primary care practices for services paid for by Medicaid and Medicare. Payment for the referrals would fly in the face of the AKS proscription against remuneration to induce referrals for services reimbursed by a federal or state health care program. The AKS does not, however, preclude all payment or incentives for projects that seek to change referral patterns. It requires, however, that PPS Leads and participating providers, as they structure and evaluate payments and performance metrics, distinguish between paying for services that can result in a referral, such as counseling or enhanced data exchange, and paying for the referral itself or payment based on the volume of referrals.

DSRIP performance incentives must also comply with the Civil Monetary Penalties Law (CMP). Among other prohibitions, the CMP bars any hospital from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit medically necessary services.[17] Until 2015, the CMP barred payments that could induce even medically unnecessary services, except for payments in the context of managed care plans. The CMP was amended in 2015 to narrow its scope to "medically necessary" services to permit incentives aligned with federal and state health reform.[18] This is a hugely important amendment for DSRIP, with its primary goal of reducing unnecessary hospital admissions and use by 25%. By its terms, the CMP applies solely to incentives by hospitals to physicians, but withholding medically necessary services poses a host of risks, including malpractice liability and regulatory enforcement, which means that both hospital-led and Newco-led PPSs should address this risk more broadly as they craft project metrics and performance incentives. For example, a performance metric based solely on reduction in referrals to hospitals and ED visits, without a focus on quality of care or the services provided, will reward a decrease in medically necessary ED visits as well as medically unnecessary visits.

Seeking Safeguards: OIG Advisory Opinions on Gainsharing and Pay-for-Performance

No AKS safe harbor exists for performance incentives that would apply to many of the goals that PPSs and their participants must attain, including reduction in preventable hospital admissions and creation of an integrated delivery system. In 1999, in a Special Advisory Bulletin, the HHS Office of Medicaid Inspector General (OIG) advised that arrangements by which hospitals share cost savings with physicians (generally referred to as gainsharing) would violate the CMP, pointing to the strict prohibition in the statute as well as concerns about the quality of care and potential for fraud and abuse.[19] Notably, the OIG stated that a payment need not lead to an actual reduction in treatment to violate the CMP, as long as the hospital knows that it may influence physicians to limit medical services to their patients. Nonetheless, starting in 2001, the OIG issued a series of favorable opinions of gainsharing arrangements addressing both the CMP and AKS, and two favorable opinions of pay-for-performance arrangements between hospitals and physicians for compensation based on quality metrics and cost savings.[20]

The favorable OIG gainsharing and pay-for-performance opinions found that while the arrangements implicated the AKS and CMP, sufficient safeguards were in place to reduce the risks posed. Notably, in general, the Advisory Opinions address gainsharing arrangements for surgical procedures, such as cardiac catherization, that rely on highly specific clinical protocols and cost-reduction attained through savings related to product standardization, reduced waste of medical supplies and similar cost-saving measures. While not a good fit for many DSRIP projects that target cost savings through broader goals, such as improved care coordination, the Advisory Opinions identify useful factors for consideration as payments are designed for DSRIP and other state and federal reform initiatives.

In considering the risks to CMP compliance and the potential impact on the quality of care for patients, the OIG Advisory Opinions identified certain common elements of the arrangements that supported the decision not to impose sanctions. Among other factors, the OIG Advisory Opinions pointed to the following:

- Credible support that the initiative will improve quality and is unlikely to have adverse effects;

- Specificity of quality measures to assure that the focus is quality, not cost;
- Specific cost-saving opportunities identified based on analysis of historical practices by physicians;
- Hospital committee will monitor quality targets to protect against inappropriate reduction in patient care;
- Incentives are transparent, including written disclosure to patients;
- An agreement in writing for longer than one year; and
- Incentives to physicians are capped and based on aggregate performance, not based on cost savings attained by physicians individually.

The Advisory Opinions also shed light on safeguards to reduce the risks of an AKS violation. In addition to some of the safeguards noted above, the OIG considered the fact that for pay-for-performance arrangements: (i) payments were at FMV; (ii) compensation did not vary with the volume of patients treated; and (iii) participation was open to all existing members of the medical staff.[21]

Certain elements identified as safeguards by the OIG, including reliance on written agreements, implementation of national standards for quality, caps on incentives to physicians, and baseline performance to assess improvement, lend themselves well to DSRIP projects. In addition, given the strong focus of DSRIP on reducing cost and preventable hospital use and admissions as well as the sharp shift in incentives to support this change in the last three years of the program, PPS Leads and participating providers should adopt safeguards to reduce the risk of a CMP violation.

Stepping back from the specific elements of the AKS safe harbors and the safeguards identified by the OIG Advisory Opinions, DSRIP provides additional safeguards that address the underlying concerns of the AKS and CMP: (i) increased costs to federal and state health care programs due to inappropriate referrals; (ii) disguised payments for referrals; (iii) reduction in the quality of care; (iv) incentives to care for only the healthiest patients; and (v) reduction in medically necessary services.

DSRIP seeks to achieve the triple aim of reduced cost, improved quality, and population health management. With respect to overutilization, DSRIP aims to dramatically reduce the cost of care for the Medicaid program, by shifting from more costly, preventable treatment in the inpatient setting to outpatient care and increasing access to primary care. DSRIP projects are designed to recruit and manage the Medicaid beneficiaries who are hardest and most costly to treat, including patients with substance abuse and mental health conditions. PPS Leads must create transparent fund flow plans that will guide payments to participating organizations for projects delineated by NYSDOH. NYSDOH has approved the detailed implementation plans submitted by each PPS Lead, and will evaluate performance on a quarterly basis. PPS Leads are required to use evidence-based protocols for project implementation and report to NYSDOH on standardized metrics that will be publicly posted. In short, while the exceptional level of NYSDOH oversight and prescriptive DSRIP requirements are a burden for PPS Leads and participants alike, the unusual degree of state involvement provides significant safeguards likely to be considered by the OIG as it evaluates gainsharing and pay-for-performance incentives.[22]

Conclusion

DSRIP programs in varying forms have been implemented in eight states, with negotiations ongoing between CMS and other states to initiate the program. Lessons learned and the challenges confronted in New York State offer valuable insight for national policy and practice. OIG Advisory Opinions on gainsharing and performance payments, as well as the 2014 Proposed Rule to expand AKS safe harbors and permissible payments under the CMP to Medicare and Medicaid beneficiaries, reflect mounting recognition of the need to align application of the fraud and abuse laws with federal and state health reform.[23] Federal and state governments in their roles as policy makers and regulators need to close that gap. CMS and the OIG adopted waivers for the Shared Savings Program and most recently for the bundled payment program for joint replacement.

They should do the same for DSRIP programs, crafting waivers of the fraud and abuse laws to support the novel payments that lead organizations must make for infrastructure development, project implementation, and performance payments.[24] Even if consistent with aims set by state policy, metrics for DSRIP performance, as established by state agencies, by lead entities, and by participating organizations must be devised so they are compatible with the fraud and abuse laws. Finally, given the converging shift in incentives by public and private payers to reduce utilization, training should be an essential element of program implementation so that the incentives, as translated in the direct interaction with patients, are not misunderstood or misapplied.

Endnotes

1. Deborah Bachrach, William Bernstein, Jared Augenstein, Mindy Lipson & Reni Ellis, *Implementing New York's DSRIP Program: Implications for Medicaid Payment and Delivery System Reform*, THE COMMONWEALTH FUND (April 2016), http://www.commonwealthfund.org/~/media/files/publications/fund-report/2016/apr/1871_bachrach_implementing_new_york_dsrip_v4.pdf?la=en. Other states currently implementing some form of DSRIP program are: Alabama, California, Kansas, Massachusetts, New Hampshire, New Jersey and Texas.
2. For extensive information about the 25 performing provider systems (PPSs) approved by the New York State Department of Health (NYSDOH) and DSRIP projects, milestones, funding, regulatory requirements and mandated elements for the integrated delivery systems PPSs must build, among other information, *see Delivery System Reform Incentive Payment (DSRIP) Program*, NEW YORK STATE DEPT. OF HEALTH, http://www.health.ny.gov/health_care/medicaid/redesign/dsrip/ (last visited May 26, 2016).
3. Medicare Program; Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992 (Nov. 2, 2011).
4. *See id.*; Federal Trade Commission and United States Department of Justice, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67026 (Oct. 28, 2011); I.R.S. Notice 2011-20.
5. 18 N.Y.C.R.R. Part 521.
6. Delivery System Reform Incentive Payment (DSRIP) Program, *DSRIP Compliance Guidance 2015-01—Revised, Special Considerations for Performing Provider System (PPS) Leads' Compliance Programs*, NYS OFFICE OF MEDICAID INSPECTOR GENERAL (Sep. 1, 2015), https://www.omig.ny.gov/images/stories/compliance_alerts/20150901_DSRIP_CompGuidance_2015-01_Rev.pdf ("Guidance Statement"); *OMIG Webinar Materials: OMIG Call Recording*, NEW YORK STATE DEPT. OF HEALTH (Feb. 26, 2015), https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/webinars_presentations.htm; *OMIG Webinar Materials: OMIG Call Recording*, NEW YORK STATE DEPT. OF HEALTH (Apr. 7, 2015), https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/webinars_presentations.htm.
7. *See* Guidance Statement, *supra* note 6.
8. *See* Delivery System Reform Incentive Payment (DSRIP) Program, *DSRIP Compliance Guidance 2015-02, Frequently Asked Questions by Performing Provider System (PPS) Leads Relative to Compliance Programs*, NEW YORK STATE OFFICE OF MEDICAID INSPECTOR GENERAL AND NEW YORK STATE DEPARTMENT OF HEALTH (July 15, 2015), https://www.omig.ny.gov/images/stories/compliance_alerts/20150715_dsrip_faqs.pdf.
9. *Special Considerations for Performing Provider System (PPS) Leads' Compliance Programs*, *supra* note 6.
10. *OMIG Webinar: PPS Compliance Program*, *supra* note 6.
11. *DSRIP Program FAQs*, *supra* note 8.
12. Federal Stark Law, 42 U.S.C. § 1395nn; NYS Prohibition on Provider Referrals Law (also referred to as the State Stark Law) NYS Public Health Law, § 238-a; Federal Anti-Kickback Law, 42 U.S.C. § 1320a-7b(b); NYS Anti-Kickback Law, N.Y. Educ. Law § 6530(18); Civil Monetary Penalties Law, Social Security Act § 1128, 42 U.S.C. § 1320a-7a.
13. 42 U.S.C. §§ 1395nn(a)1-2.
14. 42 U.S.C. § 1395nn(a)2.
15. For Stark Law exceptions *see* 42 U.S.C. §§ 1395nn(b)-(e).
16. *Revised DSRIP Actively Engaged: Project Specific Definitions and Clarifying Information*, NEW YORK STATE DEPARTMENT OF HEALTH, 11 (Oct. 28, 2015), https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/docs/2015-10-28_actively_engaged_definitions.pdf.
17. Civil Monetary Penalties Law, Social Security Act § 1128A, 42 U.S.C. § 1320a-7a.
18. Medicare Access and CHIP Reauthorization Act of 2015 § 512, Pub. L. No. 114-10, 129 Stat. 87.
19. *Gainsharing Arrangements and Civil Monetary Penalties for Hospital Payments to Reduce or Limit Services to Beneficiaries*, OFFICE OF THE INSPECTOR GENERAL (July 1999), http://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm.
20. *See, e.g.*, OIG, Advisory Opinion No. 07-22 (Jan. 14, 2008); OIG, Advisory Opinion No. 06-22 (Nov. 16, 2006); OIG, Advisory Opinion No. 08-16 (Oct. 7, 2008); OIG, Advisory Opinion No. 12-22 (Jan. 7, 2013). In 2008, CMS issued a proposed rule to create a new exception for gainsharing under the Stark Law. 73 Fed. Reg. 38502 (July 7, 2008). The rule has not yet been adopted in final form.
21. OIG, Advisory Opinion Nos. 08-16, 12-22.
22. *See* discussion of safeguards in proposed regulations amending safe harbors to the AKS and exceptions to the CMP definition of remuneration, 79 Fed. Reg. 59726 (Oct. 3, 2014).
23. 79 Fed. Reg 59725 (Oct. 3, 2014).
24. *See* waivers granted by CMS for other innovation programs, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.

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