



HEALTH LAW VITALS A Healthcare Newsletter from Haynes and Boone, LLP

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QUICK SHOTS

OSHA deadline for electronic submission of injury and illness records to a public website is Dec. 1, 2017.

[Read more.](#)

ONC issues guidance related to patient access.

[Read more.](#)

FDA releases compliance guide for small businesses under FSMA Intentional Adulteration Rule.

[Read more.](#)

UPCOMING EVENTS

American Health Lawyers Association Distance Learning

Increasing Access to Care: Telemedicine and the Law

Michelle "Missy" D. Apodaca

October 17, 2017

Online at healthlawyers.org

Reigniting the Debate about Restrictions on Physician-Owned Hospitals

Kenya S. Woodruff and Neil Issar



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Earlier this year, Congressman Sam Johnson (R-TX) and Senator James Lankford (R-OK) introduced the Patient Access to Higher Quality Health Care Act of 2017 (H.R. 1156 / S.B. 1133), a proposed law to repeal certain sections of the Affordable Care Act ("ACA") that have effectively restricted the expansion and construction of physician-owned hospitals ("POHs").

Specifically, the ACA currently prohibits physicians' referrals of Medicare or Medicaid patients to any hospital in which they have an ownership share if the hospital was formed after December 31, 2010 (prohibiting POHs from utilizing the "whole hospital" or "rural provider" exceptions to the physician self-referral law). The ACA also prohibits POHs from increasing their aggregate percentage of physician-ownership after March 23, 2010. With certain exceptions, a POH may not increase its aggregate number of operating rooms, procedure rooms, or beds above the number for which it was licensed as of March 23, 2010 (or the later effective date of the hospital's Medicare provider agreement).¹

The bills reawakened a debate about the pros and cons of POHs. Critics - mainly the non-profit community and for-profit hospitals - remain concerned that POHs "cherry pick" healthier patients undergoing procedures with higher reimbursement rates. Non-POHs are then left to scavenge on low-reimbursement or non-paying patients, which threatens their existence in an increasingly competitive healthcare environment. Critics also accuse POHs of providing no benefit in terms of cost savings or patient outcomes.

On the other hand, advocates of POHs maintain that increased physician participation in hospital governance and decision-making can streamline operational costs and processes. This allows POHs to manage resources more efficiently and provide high-quality care in a more cost-effective way than non-POHs. Advocates maintain that hospital opposition to POHs is merely a matter of economic protectionism and POHs do not actually present any danger to patient care or healthcare costs. In fact, repealing the ban on new POHs has been part of

several Republican efforts for healthcare reform and was included in Speaker of the House Paul Ryan’s “Better Way” white paper.²

Studies have found the quality of care provided at POHs to be equal to, or in some cases better than, care at non-POHs across a range of metrics, including process measures, mortality rates, and readmission rates.³ In FY 2017 of the CMS Hospital Value-Based Purchasing Program, which rewards hospitals for delivering high quality of care, adhering to clinical best practices, and improving the patient experience, seven of the top 10 and 40 of the top 100 hospitals were physician-owned.⁴ And for the fifth year in a row, a POH was ranked first in the nation. Studies even found higher patient satisfaction at POHs.⁵ All this despite POHs comprising only five percent of all hospitals in the nation.

Studies also showed that costs and Medicare payments at POHs were similar to, or lower than, those at non-POHs.⁶ An analysis of CMS payment data by Avalon Health Economics demonstrated that POHs saved Medicare \$3.2 billion over 10 years.⁷ In 2014 alone, POHs resulted in more than \$258 million in Medicare savings.

The Federation of American Hospitals and the American Hospital Association have come out in strong opposition to the proposed bills, presenting commissioned studies that confirmed their concerns regarding POHs. Similarly, the Chamber of Commerce has opposed any efforts to unwind the ACA’s protections against self-referral to POHs.

While both Patient Access to Higher Quality Health Care Act bills remain in committee as of August 2017, their introduction has raised broad questions: Do the ACA restrictions on POHs reduce patients’ access to high-quality healthcare? Should POHs that meet certain quality or cost saving thresholds be exempted from the ACA’s restrictions? Would

competition stimulated by POHs be good for the American healthcare industry? And will politicians and lawmakers consider the recent data regarding POHs when determining the appropriate role of POHs in our delivery system moving forward?

¹ Elizabeth Plummer & William Wempe, *The Affordable Care Act’s Effects on the Formation, Expansion, and Operation of Physician-Owned Hospitals*, 35 HEALTH AFF. 1452 (2016).

² See Paul Ryan, *A Better Way: Our Vision for a Confident America* 32–33 (June 22, 2016) (“Lifting the ban on physician-owned hospitals will make markets more competitive by driving down prices and increasing quality.”).

³ See, e.g., Daniel M. Blumenthal et al., *Access, quality, and costs of care at physician owned hospitals in the United States: observational study*, 351 BMJ 1, 5 (2015).

⁴ R. Blake Curd, *Physician-owned hospitals: Competition that drives quality*, THE HILL (Feb. 16, 2017).

⁵ Daniel K. Lundgren et al., *Are the Affordable Care Act Restrictions Warranted? A Contemporary Statewide Analysis of Physician-Owned Hospitals*, 31 J. ARTHROPLASTY 1857, 1859 (2016); see also Adriana G. Ramirez et al., *Physician-owned Surgical Hospitals Outperform Other Hospitals in the Medicare Value-based Purchasing Program*, 223 J. AM. COLL. SURG. 559, 563 (2016) (physician-owned surgical hospitals “demonstrate better patient satisfaction related to specialized training of providers and staff, similar or better patient outcomes, and lower costs hypothesized to occur as a result of aligning manager and leadership salaries with growth and profit of the organization.”).

⁶ Blumenthal, *supra note 3*; see also Press Release, Physician Hospitals of America, *55 National and State Organizations Voice Support for Higher Quality Healthcare* (May 17, 2017).

⁷ John T. Gill, *Physician-Owned Hospitals Should Be Included In ACA Repeal Bill*, D HEALTHCARE (Feb. 10, 2017).

Recent Updates to the OIG’s Work Plan

Christopher Rogers and Lisa M. Prather



Christopher Rogers

Lisa M. Prather

In mid-August, the United States Office of Inspector General (“OIG”) announced updates to its Work Plan and established that it will now post updates to the Work Plan on a monthly basis instead of only

once or twice per year. The Work Plan sets forth the OIG's current projects and areas of focus, including audits currently in process or anticipated to start, based on areas of the U.S. Department of Health and Human Services programs the OIG considers contain risk or need attention. The OIG's list of active items on its Work Plan has more than 200 entries, with 37 items having been added this summer alone (18 items added in June, 14 items added in July, and five items added in the first two weeks of August). Some of the matters added this summer include:

- An audit of how states are monitoring their opioid treatment programs
- A review of certain Medicare payments for telehealth services
- An audit of the appropriateness of Medicare Part B payments for psychotherapy services
- An assessment of the value of the Patient Safety Organization Program among hospitals
- A review of the quality measure data reported by Medicare Shared Savings Program Accountable Care Organizations

For more details about the OIG's Work Plan, please visit the [OIG's website](#).

Pharmaceutical Manufacturers Still Without Clear Guidance on Appropriate Safeguards for Copayment Coupons

Kenya S. Woodruff and Jennifer S. Kreick



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While pharmaceutical manufacturers are continuing to face scrutiny for prescription drug prices,¹ they are still without clear

guidance from government regulators on appropriate safeguards for the use of copayment coupons. This lack of guidance leaves pharmaceutical manufacturers using copayment coupon programs, including print coupons, electronic coupons, debit cards, and direct reimbursements, with potential compliance exposure at a time when their pricing and payment policies and practices are being analyzed by the media, legislators, and the public.

In September 2014, the U.S. Department of Health and Human Services Office of Inspector General ("OIG") issued a Special Advisory Bulletin on pharmaceutical manufacturer copayment coupons concurrently with a report conducted by the OIG, Office of Evaluation and Inspections ("OEI") finding that pharmaceutical manufacturer safeguards may not prevent copayment coupon use for Medicare Part D drugs. According to the OIG, copayment coupons offered to insured patients to reduce or eliminate their out-of-pocket copayments for specific brand-name drugs may implicate the federal Anti-Kickback Statute, the False Claims Act, and the Civil Monetary Penalties Law. The federal Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any federal health care program (including, but not limited to, Medicare and Medicaid). A claim that includes items or services resulting from a violation of the federal Anti-kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. The Civil Monetary Penalties Law authorizes the imposition of civil monetary penalties if a person offers or transfers remuneration to a Medicare or state health care program (including Medicaid) beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program.

The OIG stated its concern that copayment coupons may cause federal health care program beneficiaries and their physicians to choose an expensive brand-name drug when a less expensive and equally effective generic or alternative drug is available, resulting in higher costs to federal health care programs. While the OIG recognized that copayment support may benefit beneficiaries by encouraging adherence to medication regimens (especially when copayments are so high as to be unaffordable to many patients), it stated that pharmaceutical manufacturers have the option of donating to independent charities that provide financial support to patients without regard for the particular medication a patient may be using, and referred to its guidance on Independent Charity Patient Assistance Programs.

The OIG cited the OEI's report finding that the measures that manufacturers reported having in place to prevent use of copayment coupons to fund copayments for drugs paid for by Medicare Part D may not prevent all such use. While the OEI report focused on drugs paid for by Medicare Part D, the OIG bulletin focused more broadly on all federal health care programs. The OEI report found that although all manufacturers place notices on certain coupons or coupon materials that federal health care program beneficiaries are not eligible to use the coupons, such notices may not appear on all coupon formats. In addition, while manufacturers may also use claims edits in the processing of some of their coupons, the OEI report stated that claims edits may not reliably identify all claims submitted in connection with drugs paid for by Medicare Part D. Finally, the report found that coupons are not transparent in the pharmacy claims transaction system to entities other than manufacturers, such as Part D plans, which impedes others from identifying and monitoring the use of coupons for drugs paid for by Medicare Part D.

The OEI report recommended that the Centers for Medicare & Medicaid Services ("CMS") cooperate with industry stakeholder efforts to improve the reliability

of claims edits and make copayment coupons universally transparent and identifiable in pharmacy claims transactions.

The OIG ended with a reminder that regardless of future actions by CMS, the parties offering the coupons ultimately bear the responsibility to operate copayment coupon programs in compliance with federal law, and the failure of pharmaceutical manufacturers to take appropriate steps to ensure that copayment coupons do not induce the purchase of federal health care programs items or services may be evidence of intent to induce the purchase of drugs paid for by these programs in violation of the federal Anti-Kickback Statute. Despite this firm warning, to our knowledge, CMS has yet to issue clear guidance on improving the reliability of mechanisms to determine when copayment coupons are used, and there is relatively little guidance on what constitutes "appropriate steps" for ensuring that copayment coupons are not used to purchase drugs paid for by federal health care programs.

For example, in OIG Advisory Opinion No. 16-07 issued on June 20, 2016, the OIG determined that it would not issue sanctions for an arrangement involving a savings card that allowed individuals enrolled in commercial insurance plans and Medicare Part D beneficiaries to receive a discount when they filled their prescriptions for a drug that was statutorily excluded from coverage under Medicare Part D. Under the arrangement, Part D beneficiaries could receive discounts on out-of-pocket costs greater than \$15, up to a maximum benefit of \$75 per prescription, on up to 12 prescriptions for the medication. The OIG found that the arrangement did not induce the purchase of a specific item for which payment may be made by Medicare Part D because the requestor takes measures to ensure claims are not submitted to Medicare Part D plans, including: (i) requiring card activation online or by telephone, and if the individual uses Medicare Part D for prescription drug coverage, the individual must agree that he or she will

not submit claims for the drug to his or her Medicare Part D plan; (ii) using a vendor to process pharmacy claims and contractually requiring the vendor to use claims data to detect, in real time, attempted card use by individuals who are ineligible to participate in the arrangement; and (iii) distributing written materials to pharmacies with detailed processing instructions (i.e., the pharmacy must process Medicare Part D beneficiaries as cash-paying customers, and certify that the pharmacist has not submitted and will not submit a claim for reimbursement for the prescription to any state or federal health care program or other governmental program).

The OIG stated that while these measures are not infallible and normally might be insufficient to allow it to conclude that the card cannot be used to purchase an item payable by Medicare Part D, the unique circumstances here serve as an effective backstop to prevent the coupon program from inducing the purchase of a drug payable by Medicare Part D. This is because even if a Part D beneficiary or a pharmacy filling a Part D beneficiary's prescription submitted a claim to a Medicare Part D plan for the drug, the claim would be denied due to the drug's exclusion from coverage.

States may also have laws similar to the federal Anti-Kickback Statute that could apply more broadly to limit or prevent the use of copayment coupons for commercial plans. For example, Massachusetts recently extended its exception to its own anti-kickback statute for copayment coupons when there is no AB rated generic equivalent drug until July 1, 2019.

Although clear guidance from regulators regarding appropriate safeguards for the use of copayment coupons may be lacking, pharmaceutical manufacturers should ensure that they have effective compliance programs in place, review state laws, implement any applicable safeguards identified by the OIG as beneficial (such as ensuring clear and conspicuous notices appear on all coupon formats), and monitor and audit copayment coupon programs on a regular basis to identify ways to improve compliance.

¹ See, e.g., U.S. Dep't of Health & Human Svcs. Office of Inspector General, OIG Work Plan 2017, [Increase in Prices for Band-Name Drugs Under Part D](#).

We'd like to hear your feedback and suggestions for future newsletters. Please contact:



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