

Recent Development

The Shift Toward Site-Neutral Payment Policy in Medicare

*Rachel Page**

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INTRODUCTION

Under the traditional Medicare system, the government pays more for a patient to have an ultrasound performed in a hospital outpatient department than for the patient to have the same ultrasound in a physician’s office.¹ The fact that the same service could result in higher

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1. Margot Sanger Katz, *When Hospitals Buy Doctors’ Offices, and Patient Fees Soar*, N.Y. TIMES (Feb. 6, 2015), <https://www.nytimes.com/2015/02/07/upshot/medicare-proposal-would->

reimbursement if performed in a hospital-owned entity is cited as one of the factors that incentivizes health systems to buy physician practices.²

Each type of health care provider generally receives payment under reimbursement systems that are specifically tailored to that provider.³ These separate payment systems are designed to accommodate for the cost of providing care in different settings and different patient populations that each provider serves.⁴ Because hospital outpatient departments are more likely to treat sicker, poorer patients and have higher overhead costs, Medicare traditionally reimbursed hospital outpatient departments at a higher rate than ambulatory surgical centers (“ASCs”) or physicians’ offices for the very same service.⁵

In an effort to respond to and reduce these payment disparities, Congress included language in section 603 of the Bipartisan Budget Act of 2015 (“Act”) that effectively mandated that providers receive payment

even-out-doctors-pay.html. *See also* MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 75 (Mar. 2014) [hereinafter MEDPAC 2014 REPORT] (“Medicare pays more than twice as much for a level II echocardiogram in an outpatient facility (\$453) as it does in a freestanding physician office (\$189).”).

2. *See, e.g.,* Erica Teichart, *Site-Neutral Pay Changes Leave Hospitals’ Off-Campus Sites with Big Challenges*, MOD. HEALTHCARE (Nov. 5, 2016), <http://www.modernhealthcare.com/article/20161105/MAGAZINE/311059967> (providing an explanation as to why health systems buy physician practices).

3. Amanda Cassidy, *Health Policy Brief: Site-Neutral Payments*, HEALTH AFF. (July 24, 2014), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=121; Juliette Cubanski et. al, *A Primer on Medicare: Key Facts About the Medicare Program and the People It Covers*, KAISER FAM. FOUND. (Mar. 20, 2015), <http://kff.org/report-section/a-primer-on-medicare-how-does-medicare-pay-providers-in-traditional-medicare/>. Even in Accountable Care Organizations, providers generally receive separate payments under a fee-for-service system, but have the opportunity to share in the savings (and the losses, in certain risk options) associated with providing more cost-efficient, quality care than beneficiaries of like characteristics would have received. U.S. DEP’T OF HEALTH & HUMAN SERVS., CTRS. FOR MEDICAID & MEDICARE SERVS., ICN 907406, ACCOUNTABLE CARE ORGANIZATIONS: WHAT PROVIDERS NEED TO KNOW 3 (2016), https://www.cms.gov/medicare/medicare-fee-for-service-payment/sharesavingsprogram/downloads/aco_providers_factsheet_icn907406.pdf.

4. Cassidy, *supra* note 3.

5. Demiralp et al., *Comparison of Care in Hospital Outpatient Departments and Physician Offices*, KNG HEALTH CONSULTING LLC (Feb. 2015), <http://www.aha.org/content/15/hopdcomparison.pdf>. *But see* U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-16-189, MEDICARE: INCREASING HOSPITAL-PHYSICIAN CONSOLIDATION HIGHLIGHTS NEED FOR PAYMENT REFORM 18 (2015) [hereinafter GAO-16-189] (“Our report does not make [] an assertion [that patients treated at hospital outpatient departments are not sicker than those treated at physician offices], but does include our finding that beneficiaries residing in counties with higher levels of vertical consolidation were not sicker, on average, than beneficiaries residing in counties with lower levels of consolidation.”); *see also infra* Part I.B (identifying governmental reports that examine this disparity in payment). Medicare also reimburses at different levels for services performed on an inpatient basis—as opposed to an outpatient basis—but this Recent Development primarily focuses on the differential in payments between hospital outpatient departments, ASCs, and physicians’ offices.

for outpatient services under the same methodology, regardless of whether the services were delivered in a provider-based, hospital-owned outpatient department or a physician-owned outpatient department.⁶ On November 2, 2016, the Centers for Medicare and Medicaid Services (“CMS”) released the final rules that implemented this site-neutral payment policy amidst both praise and criticism for the shift toward site-neutral payment methodologies.⁷

I. BACKGROUND

A. Medicare’s Payment Structure for Hospitals Prior to the Bipartisan Budget Act of 2015

Hospital expenditures were over \$1 trillion in 2015, and health care spending in general is expected to continue growing at faster rates than in the recent past.⁸ Medicare pays hospitals prospectively using a predetermined, fixed amount that it calculates based on a classification system and the type of service. The classification system the government uses for inpatient services varies from the classification it uses for outpatient services.⁹

Starting in 2000, Medicare paid hospitals for most outpatient services using the hospital outpatient prospective payment system (“OPPS”).¹⁰ Unlike the inpatient prospective payment system—which distributes one payment for all care and services provided during a patient’s hospital stay based on the patient’s diagnosis or diagnoses—the OPSS distributes separate payments based on the specific services performed.¹¹ The OPSS

6. Bipartisan Budget Act of 2015, Pub. L. No. 114-74, § 603, 129 Stat. 584, 597 (amending 42 U.S.C. § 1395l(t)).

7. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. 79,562 (Nov. 14, 2016).

8. *NHE Fact Sheet*, CTRS. FOR MEDICAID & MEDICARE SERVS., <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html> (last updated Dec. 2, 2016, 1:23 PM).

9. Amanda Cassidy, *Health Policy Brief: The Two-Midnight Rule*, HEALTH AFF. (July 22, 2015), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=121 (“In many cases, the same service could be provided on an inpatient or an outpatient basis, but Medicare pays hospitals very differently for inpatient versus outpatient care.”).

10. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. at 79,753 (Nov. 14, 2016); THOMAS C. FOX ET. AL., HEALTH CARE FINANCIAL TRANSACTIONS MANUAL § 17:21 (West 2016).

11. Cassidy, *supra* note 9. For inpatient services, Medicare pays hospitals using base rates that correspond to categories of diagnoses called Diagnostic Related Groups (“DRGs”). Cubanski, *supra* note 3. Medicare pays the hospital a specified amount for each discharge based on the average cost to treat an inpatient with similar characteristics, such as age, sex, and other diagnoses. FOX ET. AL., *supra* note 10, § 17:5. Therefore, if a hospital discharges an inpatient quicker than average and spends less than the average-expected cost, that hospital may be eligible to keep the

calculates payment rates for outpatient services by using ambulatory payment classifications (“APCs”) and conversion factors, but it may also adjust payment based on geographic factors or the type of service.¹²

Traditionally, off-campus outpatient departments or facilities of hospitals received payments under the OPPTS if the department was designated as a provider-based entity.¹³ To receive provider-based status, CMS required the department to show integration with the hospital that owned it (i.e., the “main provider”) and submit an attestation to that effect.¹⁴ CMS also required off-campus facilities to operate under the ownership and control of the main provider, receive as much supervision as the main provider gives to its other departments, and be located within a thirty-five-mile radius of the main provider’s campus.¹⁵

Receipt of provider-based status permitted the outpatient department to bill as if it were a hospital department (as opposed to a freestanding entity).¹⁶ Medicare typically remitted two payments to off-campus, provider-based hospital outpatient departments.¹⁷ The first payment covered facility costs for items and services, such as surgical supplies and

difference between the actual cost of care and the DRG amount. Medicare may also reduce payments to certain hospitals, however, such as those that have higher Medicare readmission rates. Cubanski, *supra* note 3.

12. Cassidy, *supra* note 3; Cubanski, *supra* note 3. Some services are packaged in the hospital outpatient setting, but paid separately when delivered in a physician’s office. Cubanski, *supra* note 3.

13. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. at 79,753.

14. Specifically, a provider must show: (1) common licensure with the main provider if permitted by state law; (2) integrated clinical services, such as the granting of clinical privileges at the main provider to the professional staff at the outpatient facility and common medical staff or professional committees; (3) financial integration between the main provider and outpatient facility, as evidenced by shared income and expenses; and (4) public awareness of the relationship between the main provider and outpatient facility. 42 C.F.R. § 413.65(d) (2012). A “main provider” is one that “creates, or acquires ownership of, another entity to deliver additional health care services under its name, ownership, and financial and administrative control.” *Id.* § 413.65(a). For off-campus facilities, the main provider must submit an attestation that the facility seeking provider-based status complies with the applicable requirements. *Id.* § 413.65(b). Hospital outpatient departments also must comply with a number of additional requirements, such as compliance with antidumping rules, compliance with the hospital’s provider agreement with Medicare, and treatment of all Medicare patients as hospital outpatient patients instead of physician-office patients. *Id.* § 413.65(g).

15. *Id.* § 413.65(e).

16. In essence, a provider-based department is “considered to be part of the hospital,” whereas a freestanding entity is not. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. 45,604, 45,682 (proposed July 14, 2016) (to be codified at 42 C.F.R. pt. 416).

17. Cassidy, *supra* note 3; Lawrence W. Vernaglia & Jeffrey R. Bates, *Hospital Self-Audits of “Provider-Based” Status*, COMPLIANCE TODAY 33, 35 (Oct. 2012).

nursing services. The second payment covered the physician's professional services.¹⁸

Entities such as physicians' offices that provide outpatient services, but do not have provider-based status (i.e., freestanding entities), receive a single payment under the Medicare Physician Fee Schedule ("MPFS") that includes the costs for both facility and professional services.¹⁹ Under the MPFS, freestanding physicians' offices receive a fee that reflects three components: physician work, practice expense, and professional liability insurance.²⁰ The practice expense component paid to a freestanding entity is usually greater than the practice expense fee paid to a provider-based, hospital-owned outpatient department, to account for the physicians' overhead expenses like clinical staff and medical supplies.²¹ Despite the higher practice expense component, however, the combination of fees paid to the provider-based, hospital-owned outpatient department is usually higher than the total fee paid to a freestanding entity.²²

The federal government pays ASCs, facilities that generally provide outpatient surgical procedures to patients who do not require an overnight stay, pursuant to the ASC Payment System, which uses an APC classification system similar to the OPPI.²³ ASCs, however, receive less than hospitals do because of lower conversion factors.²⁴ Payment levels are "generally . . . higher when the service is provided in a provider-based entity."²⁵ Therefore, some governmental entities called for Medicare to equalize reimbursement structures for the various sites as a way to lessen incentives to provide services in the higher-paid sites and decrease health care costs.

B. The Push for Site-Neutral Payments

Because Medicare previously paid "different rates for the same

18. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. at 79,710.

19. MEDPAC 2014 REPORT, *supra* note 1, at 75.

20. *Id.* at 80.

21. *Id.*

22. *Id.*

23. 2 EMILY JANE COOK, HEALTH LAW PRACTICE GUIDE § 24:20 (2016).

24. Shawn Mathis, *Closing in on Health Care—Associated Infections in the Ambulatory Surgical Center*, 33 J. LEGAL MED. 493, 496 (2012); MEDPAC, *Ambulatory Surgical Center Services Payment System*, http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_16_asc_final.pdf?sfvrsn=0 (last updated Oct. 2016).

25. Vernaglia & Bates, *supra* note 17. See also MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 44 (Mar. 2016) [hereinafter MEDPAC 2016 REPORT].

service, depending on where the service [was] performed,” three governmental bodies recommended changes to minimize the effects of this “financial vulnerability in Medicare’s payment policy.”²⁶ The Medicare Payment Advisory Commission (“MedPAC”)—the primary Medicare advisory body to Congress—and the Office of Inspector General (“OIG”) both urged Congress to consider using site-neutral payment policies to save money for Medicare and reduce cost sharing for beneficiaries.²⁷ In 2012, MedPAC first recommended that CMS pay the same rate for one specific outpatient service—evaluation and management office visits—regardless of whether they were provided in a hospital outpatient department or a freestanding physician’s office.²⁸ MedPAC’s 2014 report to Congress expanded upon this recommendation by pressing Congress to adopt site-neutral payment for additional outpatient service categories.

The report identified sixty-six APCs that do not require emergency standby capacity, have extra costs associated with higher patient complexity, or require additional overhead.²⁹ MedPAC found that each of these APCs should be considered for reduced payment rates that would match (or nearly match) the rates paid to freestanding offices.³⁰ Ultimately, MedPAC estimated that changing the OPPS payment rate for these APCs would reduce program spending and beneficiary cost sharing by a total of \$1.1 billion in one year.³¹

Other governmental agencies also raised concerns about the payment differentials between hospital-owned outpatient departments and other

26. GAO-16-189, *supra* note 5, at 16–17.

27. MEDPAC 2016 REPORT, *supra* note 25, at 44; OFFICE OF INSPECTOR GENERAL, A-05-12-00020, MEDICARE AND BENEFICIARIES COULD SAVE BILLIONS IF CMS REDUCES HOSPITAL OUTPATIENT DEPARTMENT RATES FOR AMBULATORY SURGICAL-CENTER APPROVED PROCEDURES TO AMBULATORY SURGICAL CENTER RATES (Apr. 2014) [hereinafter OIG 2014 REPORT].

28. MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY ix (Mar. 2012). MedPAC found the definition of the service and characteristics of the patients in the two sectors were similar enough to warrant equalized payment rates. *Id.* at xiii.

29. MEDPAC 2014 REPORT, *supra* note 1, at 77. MedPAC reviewed 450 APCs in total.

30. *Id.* For twenty-four APCs that met all five of MedPAC’s established criteria, MedPAC recommended that payment to hospital outpatient departments equal that paid to freestanding entities. For forty-two APCs that have a greater packaging of ancillary items in the OPSS, MedPAC recommended that the payment received by hospital outpatient departments be similar to that paid to freestanding entities, but could exceed those rates as necessary to account for the cost of the additional packaging. *Id.*

31. *Id.* at 78. This report also recommended addressing differences in payment rates across inpatient sites of care by revising the requirements that a Long-Term Care Hospital (“LTCH”) must meet to receive higher fees than a traditional acute care hospital and equalizing the base payment rate for nonchronically critically ill patients among LTCHs and acute care hospitals. *Id.* at 53–54.

providers. As early as 1999, the OIG expressed concerns that treating hospital-owned outpatient departments as provider-based could increase the risk of overpayments to hospitals and increase costs to beneficiaries with “questionable benefit” to the Medicare Program or its beneficiaries.³² In 2014, the OIG compared Medicare payments to hospital-owned outpatient departments and ASCs from 2007 to 2011 and found that rates paid to ASCs were “frequently lower” for surgical procedures.³³ Although the OIG recognized that “not all beneficiaries can receive services in an ASC because of the beneficiaries’ clinical needs,” the report used statistics from the Healthcare Cost and Utilization Project to classify patients as no risk, low risk, or high risk.³⁴ The OIG estimated that Medicare could save \$12 billion between 2012 and 2017, by simply adjusting the rates paid to hospital outpatient departments for no-risk and low-risk patients to match the rates paid to ASCs.³⁵

Finally, the Governmental Accountability Office (“GAO”) released a report in 2015 suggesting that consolidation between hospitals and physician practices (i.e., vertical consolidation) was on the rise.³⁶ In counties with higher levels of vertical consolidation, the GAO found that providers performed evaluation and management office visits more frequently in hospital outpatient departments, as opposed to physicians’ offices.³⁷ Ultimately, the GAO concluded that the rise in vertical consolidation exacerbated the issues associated with Medicare’s nonequalized payment policy.³⁸

C. Section 603 of the Act

To attempt to resolve these issues, Congress amended the Social Security Act to establish that off-campus hospital outpatient departments

32. OFFICE OF INSPECTOR GEN., OEI-05-98-00110, HOSPITAL OWNERSHIP OF PHYSICIAN PRACTICES 3 (Sept. 1999).

33. OIG 2014 REPORT, *supra* note 27, at 5.

34. *Id.* at 10. A high-risk patient was defined as having two or more risk factor conditions, a low-risk patient was defined as having one risk factor condition, and no-risk patients had no risk factor conditions. Risk factor conditions included characteristics such as age eighty and older, cancer, substance abuse, heart disease, arthritis, or obesity. *Id.* at 9. CMS criticized the OIG’s failure to use more specific clinical criteria to distinguish patients’ risk levels. The OIG agreed with this criticism and recommended that CMS take the necessary steps to develop a specific payment strategy for reducing OPPS payments for no-risk and low-risk patients. *Id.* at iii.

35. *Id.* at 4–5.

36. GAO-16-189, *supra* note 5, at 1. For purposes of its report, the GAO considered “vertical consolidation” to include either the hiring of physicians or the acquisition of an existing physician practice. *Id.*

37. GAO-16-189, *supra* note 5, at 12.

38. *Id.* at 16–17.

would no longer be eligible to receive payment under the OPPTS in November 2015.³⁹ Instead, the Act indicates that “payments for applicable items and services furnished by an off-campus outpatient department of a provider . . . shall be made under the applicable payment system.”⁴⁰ This broad language gives CMS—the implementing regulatory agency—the discretion to determine whether to require outpatient departments to be paid under the MPFS (i.e., receive a single payment encompassing costs for facility fees and professional services) or the ASC Payment System (i.e., receive a payment that uses APC factors, but results in a lower payment due to lower conversion factors).⁴¹

Section 603 of the Act also confers “excepted status” to off-campus outpatient departments that billed for covered outpatient department services prior to the law’s enactment on November 2, 2015.⁴² With this status, these excepted off-campus, provider-based outpatient departments can continue to bill and receive payment under the OPPTS.⁴³ Congress also provides an exception for items and services furnished by a dedicated emergency department.⁴⁴ The Congressional Budget Office estimated that this provision would save the Medicare program approximately \$9.3 billion over a ten-year period.⁴⁵

II. IMPLEMENTING THE ACT: CMS’ 2016 REGULATIONS

In 2016, CMS promulgated new regulations that clarified which departments and services would be excepted from section 603 and explained the new structure for outpatient reimbursement. Part II.A discusses the proposed rule, issued in July 2016, and Part II.B. focuses on the differences between the proposed rule and the final rule, issued in November 2016.

39. The OPPTS applies to any hospital participating in Medicare, except for Critical Access Hospitals, services furnished by Maryland hospitals that are paid under Maryland’s All-Payer Model, hospitals located outside the United States and Puerto Rico, and Indian Health Service hospitals. 42 C.F.R. § 419.20; Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. 79,562, 79,573 (Nov. 14, 2016).

40. 42 U.S.C. § 1395l(t)(21)(C).

41. Robert D. Nauman, *Bipartisan Budget Act Eliminates Provider-Based Reimbursement for Some HOPDs*, NAT’L L. REV. (Nov. 4, 2015), <http://www.natlawreview.com/article/bipartisan-budget-act-eliminates-provider-based-reimbursement-some-hopds>.

42. 42 U.S.C. § 1395l(t)(21)(B)(ii).

43. *Id.*

44. *Id.* § 1395(t)(21)(A).

45. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. 79,562, 79,700 (Nov. 14, 2016).

A. *The Proposed Rule*

CMS's proposed rule, issued in July 2016, outlined how it would implement section 603 and solicited comments from stakeholders on its proposal. CMS set forth limitations on existing outpatient departments that sought to maintain their excepted status from the site-neutral payment policy and detailed how the outpatient reimbursement structure for nonexcepted departments would differ from the existing reimbursement structure.

1. Maintaining "Excepted Status"

Pursuant to the statutory language permitting certain outpatient departments to continue billing under the OPSS, the proposed rule clarified the exceptions under section 603 by elaborating on the definition of "off-campus outpatient department of a provider" from the Act. Provider-based departments located either on, or within 250 yards of, the campus or a remote location of the hospital would be excepted from the Act and would therefore still be eligible to receive payment under the OPSS.⁴⁶ CMS also explained that it will continue to reimburse an emergency department under the OPSS for both emergency and nonemergency services, so long as it continued to meet the definition of a dedicated emergency department under 42 C.F.R. § 489.24(b).⁴⁷

Although section 603 treated off-campus outpatient departments that had billed under the OPSS prior to section 603's enactment as another exception, it did not clarify how these off-campus outpatient departments could maintain this grandfathered, excepted status.⁴⁸ The proposed rule

46. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. 45,604, 45,682 (proposed July 14, 2016) (to be codified at 42 C.F.R. pt. 416) (citing 42 C.F.R. § 413.65(a)(2)). To be considered "on the campus," the building must be immediately adjacent to the provider's main buildings, located within 250 yards of the main buildings, or located on any other area as determined on an individual case by case basis to be part of the provider's campus. 42 C.F.R. § 413.65. Outpatient departments that are located within 250 yards from a hospital's remote location (i.e., an inpatient facility that is not considered the "main provider") also fall outside the definition of an "off-campus outpatient department." *Id.*

47. 81 Fed. Reg. at 45,682. An emergency department is any department or facility of a hospital that meets one of the following requirements: (1) it is licensed as an emergency room or department under state law, (2) it is held out to the public as a place for treatment of emergency conditions without a scheduled appointment, or (3) one-third of its outpatient visits are provided for "the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment." 42 C.F.R. § 489.24.

48. Emily J. Cook et al., *CMS Proposed Rule Implements Limitations on Medicare Payments for Off-Campus Outpatient Hospital Departments*, MCDERMOTT WILL & EMERY (July 11, 2016), <https://www.mwe.com/en/thought-leadership/publications/2016/07/cms-proposed-rule-limitations-on-medicare-payments>.

did, however, place many limitations on excepted departments that wished to maintain grandfathered status. First, CMS proposed that a department would lose its excepted status if it moved or relocated from the physical address listed on the provider's hospital enrollment form as of November 1, 2015, absent extraordinary circumstances.⁴⁹ CMS expressed concerns that allowing relocation would allow hospitals to "purchase additional physician practices, move these practices into the larger, relocated facilities, and receive OPSS payment for services furnished by these physicians," which contradicted section 603's intended purpose.⁵⁰

Second, CMS proposed that an excepted department could only receive payment under the OPSS for the same *type* of services and items it furnished prior to the enactment of section 603.⁵¹ Again, CMS justified this concern on the belief that hospitals could circumvent the purpose of section 603 by purchasing additional physician practices that furnished different services and adding those physicians to existing, excepted, off-campus outpatient departments.⁵² To combat this, CMS proposed grouping services into nineteen "clinical families" and allowed excepted outpatient departments to bill only for services encompassed in each of the clinical families they had billed for prior to November 2, 2015.⁵³ To enforce this provision, CMS considered requiring hospitals to self-report the identity of all individual, excepted off-campus provider-based departments; the date each department began billing; and the clinical families of services provided by each department prior to November 2, 2015.⁵⁴ Although the Medicare enrollment process requires hospitals to report the name and address of off-campus provider-based departments,

49. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. at 45,684. The proposed rule solicited comments on how to account for hospitals that might be required to relocate to meet federal or state requirements, or due to a natural disaster, citing the disaster and extraordinary circumstances exception process under the Hospital Value-Based Purchasing Program as a potential model. *Id.* The exception process for the Hospital Value-Based Purchasing Program gives hospitals struck by a natural disaster or other extraordinary circumstances ninety days to request an exception from the program. *Id.*

50. *Id.*

51. *Id.* at 45,685.

52. *Id.*

53. *Id.* The proposed rule solicited comments on whether to adopt a specific time frame for which the billing had to occur under OPSS to be excepted. *Id.*

54. *Id.* at 45,686. Medicare does not currently collect information about the specific services performed by each off-campus outpatient's department. Though CMS required that hospitals begin requiring the use of a modifier on billing forms to signal that the services were performed in an outpatient department in 2016, the modifier does not allow Medicare to identify *which* off-campus outpatient department performed the services.

outpatient departments bill under the hospital's certification number, making it difficult for CMS to identify the specific items and services provided by each off-campus provider-based department.⁵⁵

In the case of a merger or sale of a hospital, CMS proposed that the off-campus provider-based departments of the hospital would maintain excepted status only if the ownership of the main provider transferred and the new owner accepted the Medicare provider agreement.⁵⁶ The sale of an individual, off-campus provider-based department would cause the department to lose its excepted status. CMS expressly asked for comments on both of these proposals.⁵⁷

2. Reimbursement Structure

The proposed rule discussed the current payment structure under the OPSS, wherein Medicare pays a provider-based outpatient department two separate fees—a facility fee for the hospital and a fee under the facility rate for physicians' services provided.⁵⁸ Because the sum of these fees is approximately 20 percent greater than the fees paid to a freestanding entity under the MPFS facility rate, Medicare and its beneficiaries pay more for services delivered in provider-based departments.⁵⁹ According to CMS, the opportunity to collect higher fees may also incentivize hospitals to acquire physician practices.⁶⁰ CMS explained that it would consider these concerns regarding the higher fees, the statutory language in section 603, and the “available discretion found in the statutory language” to determine how to implement the new payment structure.⁶¹

Section 603 of the Act states that outpatient department services will receive payment under “the applicable payment system” without identifying *which* payment system will be applicable, leaving CMS to fill in this large gap.⁶² For calendar year 2017, CMS proposed two options

55. *Id.* Later in the rule, CMS noted that Medicare would “expect hospitals to maintain proper documentation showing what lines of service were provided at each off-campus PBD prior to November 2, 2015.” *Id.* at 45,691.

56. *Id.* For a definition of “main provider,” see *supra* note 14 and accompanying text.

57. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. at 45,686.

58. See *supra* Part A (discussing the Medicare payment structure).

59. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. at 45,687. The proposed rule cites to the MedPAC report from March 2014, the GAO report regarding vertical consolidation, and the OIG report from June 2016 discussed in Part I.B.

60. *Id.* at 45,687.

61. *Id.*

62. *Id.* See also *supra* Part I.C. (discussing this provision).

to reimburse nonexcepted outpatient department services. Under the primary option, Medicare would pay for outpatient department services using the MPFS. Instead of paying the facility rate for physician services performed at provider-based clinics, Medicare would pay *physicians* the nonfacility rate, which incorporates a higher fee to reflect operational costs.⁶³ To recoup operational costs, hospitals would likely need to set up arrangements with these physicians. CMS explained that this would only be in place due to system discrepancies that would make it difficult to allow hospital outpatient departments to bill under a system other than OPFS for calendar year 2017.⁶⁴ Because the business arrangements between hospitals and physicians under this payment mechanism could implicate health care fraud and abuse laws, the agency sought comments on how to mitigate potential issues with the physician self-referral law (“Stark Law”), the federal Anti-Kickback Statute, and Medicare reassignment regulations.

Under the second option, hospitals could register the off-campus outpatient department as a separate facility, such as an ASC or group practice—so long as it met all applicable federal requirements associated with those systems—and instead receive payment under either of those methodologies.⁶⁵

B. *The Final Rule*

After receiving a variety of comments on the proposed rule, CMS released its final rule: a final rule with a comment period for calendar year 2017, and an interim final rule with a comment period (“Final Rule”). Most notably, CMS declined to delay implementation of the provisions of the Act, despite concerns from many commenters that the regulations would place undue burdens on hospitals and providers with little time to prepare for the sweeping changes.⁶⁶

63. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. 45,687–88. For a more detailed discussion on the professional fees paid to physicians in freestanding entities, see *supra* note 19.

64. *Id.* at 45,687, 45,689.

65. *Id.* at 45,690–91.

66. See, e.g., American Hospital Association, Comment Letter on Proposed Rule, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Aug. 26, 2016), <https://www.regulations.gov/document?D=CMS-2016-0115-0756> (“CMS must delay these site-neutral payments until it can adopt much-needed changes in order to provide fair and equitable payment to hospitals.”); MetroHealth, Comment Letter on Proposed Rule, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Sept. 6, 2016), <https://www.regulations.gov/document?D=CMS-2016-0115-1422> (“We urge CMS to delay implementation of the site-neutral provisions by one

Although CMS maintained the provisions in the proposed rule that relocation would cause a hospital to lose grandfathered status, CMS removed the provision that would have caused hospitals to lose grandfathered status for expanding their service lines.⁶⁷ The Final Rule also solidified CMS' proposal that rendered the sale of an individual outpatient department grounds for loss of grandfathered status.⁶⁸

CMS significantly altered its payment structure proposal for outpatient departments for calendar year 2017. Instead of paying physicians under the MPFS for operational costs—requiring hospitals to make arrangements with physicians to receive payments—hospitals and physicians would continue to receive separate fees for services delivered in an off-campus outpatient department. Physicians would continue to receive the facility rate under the MPFS, as they did before, and hospitals would be paid under the MPFS at approximately 50 percent of the OPFS rate.⁶⁹ While this minimizes the possible fraud and abuse and regulatory issues associated with CMS' prior proposal, the reduction in payment generated concerns about hospitals' ability to continue to provide access to care for vulnerable populations.⁷⁰

III. ANALYZING THE ANTICIPATED BENEFITS & DRAWBACKS OF SITE-NEUTRAL PAYMENT

As discussed in Part II, MedPAC, the OIG, and the GAO each issued reports indicating that hospital outpatient departments received more from Medicare under the OPFS than similar services performed in other settings, such as ASCs or freestanding physicians' offices.⁷¹ Both the proposed rule and the Final Rule suggested that Congress' primary motivation for enacting section 603 stemmed from the potential cost

year.”); American College of Cardiology, Comment Letter on Proposed Rule, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Sept. 6, 2016) (urging CMS to implement major changes, such as site-neutral payment, gradually “to minimize any impacts on patient access and quality”), <https://www.regulations.gov/document?D=CMS-2016-0115-1636>.

67. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. 79,562, 79,707 (Nov. 14, 2016).

68. *Id.* at 79,709.

69. Press Release, CMS Finalizes Hospital Outpatient Prospective Payment System Changes to Better Support Hospitals and Physicians and Improve Patient Care (Nov. 1, 2016), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-11-01.html>.

70. American Hospital Association, *CMS 2017 OPFS/ASC Final Rule Adopts Revised Site-Neutral Policy*, AHA NEWS NOW (Nov. 1, 2016), <http://news.aha.org/article/161101-cms-2017-opsasc-final-rule-adopts-revised-siteneutral-policy>.

71. See *supra* Part II.B (outlining the findings of the MedPAC, OIG, and GAO).

savings for Medicare and its beneficiaries associated with equalized payments.⁷² This Part further explains why the attempt by Congress and CMS to resolve this issue encountered both praise and criticism from the health care industry.

A. Disadvantages

To achieve cost savings for Medicare, payments to hospitals will be reduced to approximately 50 percent of what hospitals previously received under the OPPIs. Although this will bring the payment made to hospitals closer to the payment levels for ASCs and freestanding physician facilities, the letter from the American Hospital Association (“AHA”) to the Committee on Energy and Commerce argues that the higher levels of payment are necessary to account for the key differences between hospitals and other facilities.⁷³

As compared to ASCs and freestanding physician facilities, hospital off-campus outpatient departments are subject to (and will continue to be subject to) significant licensing, accreditation, regulatory, and quality requirements.⁷⁴ Hospitals also face significant overhead costs, such as those required to staff an emergency department or provide charity care.⁷⁵ Due to factors such as patient population, referral choices by physicians, and facility capabilities, ASCs, on average, tend to treat healthier patients and perform higher-profit procedures than hospital outpatient departments.⁷⁶ While ASCs generally cost less than hospitals, this disparity could be, in part, due to riskier patient populations in hospitals

72. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. at 79,700.

73. Letter from the American Hospital Association to the Honorable Fred Upton and the Honorable Joseph Pitts 3 (Feb. 12, 2016) [hereinafter American Hospital Association Letter].

74. *Id.* See also Shawn Mathis, *Closing in on Health Care-Associated Infections in the Ambulatory Surgical Center*, 33 J. LEGAL MED. 493, 498 (2012) (indicating that ASCs are typically “subject to far less regulation than hospitals,” such as less stringent Certificate of Need requirements).

75. See *How Doctor-Owned Outpatient Medical Centers Differ from Hospitals*, PBS NEWS HOUR (Sep. 12, 2014, 6:25 PM), <http://www.pbs.org/newshour/bb/doctor-owned-outpatient-medical-centers-differ-hospitals/> (suggesting that ASCs are cheaper since they do not carry “that huge hospital overhead”). In 2009, hospitals spent an average of 7.5 percent of operating expenses on community benefits, which includes charity care. Julia James, *Health Policy Brief: Nonprofit Hospitals’ Community Benefit Requirements*, HEALTH AFF. 1, 2 (Feb. 25, 2016), http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_153.pdf. The Affordable Care Act added four new community benefits requirements that hospitals must meet to maintain their tax-exempt status under 501(c)(3). *Id.* at 3.

76. Elizabeth L. Munnich & Stephen T. Parente, *Procedures Take Less Time at Ambulatory Surgery Centers, Keeping Costs Down and Ability to Meet Demand Up*, HEALTH AFF. (May 2014), <http://content.healthaffairs.org/content/33/5/764.full?sid=e53f68c1-ab29-4484-9f17-cfe0136f7452>.

that require additional resources or emergency capabilities.

The site-neutral proposals that MedPAC and the OIG introduced accounted for this possible disparity in the type of patients that hospital outpatient departments treat. MedPAC recommended reducing payment to hospitals for a select group of service classifications that do not require emergency standby capacity, have extra costs associated with higher patient complexity, or require additional overhead.⁷⁷ The OIG's report calculated savings for Medicare based on a reduction in payment only for services to no-risk and low-risk patients.⁷⁸ Though the Final Rule only applies to nongrandfathered, outpatient departments, it reduces payments for a much broader range of services. This extension will inevitably have a greater financial effect on hospitals.

Using MedPAC data, the AHA projected that enactment of site-neutral payment proposals would further reduce hospital outpatient department margins from negative 12.4 percent to negative 21.2 percent.⁷⁹ Because of the reductions in fees and the structure of the Final Rule's current exceptions, hospital organizations also suggested that savings for the Medicare program could come at the cost of reduced access to health care services for vulnerable populations due to decreased income for hospitals.⁸⁰ For example, MetroHealth System of Cleveland, Ohio indicated that loss of payment under the OPDS could discourage many hospitals from expanding their outpatient services in underserved communities.⁸¹ This would likely decrease the preventive services and continuity of care necessary to achieve desired population health

77. See *supra* Part I.B (discussing the criteria MedPAC applied when identifying the ideal APCs for site-neutral payment). See also MEDPAC 2014 REPORT, *supra* note 1, at 76 (“Higher rates for HOPD services should be limited to a select set of services. For example, some services have costs associated with maintaining standby emergency capacity.”).

78. See *supra* Part I.B (outlining the OIG's report and findings).

79. American Hospital Association Letter, *supra* note 73, at 4. This estimate accounted for the effect of other site-neutral payment policies under consideration, such as the Medicare Patient Access to Cancer Treatment Act of 2015, which would have cut cancer treatment patients from hospital outpatient departments to offset increased payments to physicians in private oncology clinics. *Id.* at 7.

80. See Illinois Health and Hospital Association, Comment Letter on Proposed Rule, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Sept. 2, 2016), <http://www.ihatoday.org/uploadDocs/1/commentltrcms1656p.pdf> (explaining its belief that CMS' proposals for site-neutral payment policies would negatively impact care for vulnerable populations in underserved communities).

81. MetroHealth, Comment Letter on Proposed Rule, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Sept. 6, 2016), <https://www.regulations.gov/document?D=CMS-2016-0115-1422>. See also *id.* at 1 (“MetroHealth continues to advocate for continued HOPD payment to facilitate integrated care and services for patients on a local level.”).

outcomes. While some larger hospital systems may be able to offset the loss of income under the site-neutral payment policy, commenters on the Final Rule expressed concern that provider-based departments of Federally Qualified Health Centers—entities that are required to provide comprehensive services in an underserved area or population⁸²—would not be exempted from the new payment policy.⁸³ Additionally, because outpatient departments that are sold individually lose their grandfathered status, commenters expressed concern that this could hinder hospitals facing financial difficulty from finding buyers for these facilities.⁸⁴ Both of these provisions could result in reduced access to services for patients in vulnerable communities.

The grandfathering provisions in section 603 could also disincentivize hospitals from expanding current outpatient departments to accommodate for additional patients or from building outpatient facilities in areas located further from the hospital, but closer to patients in need of medical services. Under the current interpretation of section 603, off-campus hospital outpatient departments can achieve grandfathered status—excepting them from the new payment policy—if the hospital was either billing under OPPTS prior to November 2, 2015, or meets certain criteria demonstrating that the department was in mid-build status as of that date.⁸⁵ But these outpatient departments can lose this grandfathered status if the department “moves or relocates from the physical address that was listed on the provider’s hospital enrollment form as of November 1, 2015.”⁸⁶ CMS intends to apply this provision strictly, as it also states

82. *Federally Qualified Health Centers*, U.S. DEP’T HEALTH & HUM. SERVS., HEALTH RESOURCES & SERVS. ADMIN., <https://www.hrsa.gov/opa/eligibilityandregistration/healthcenters/fqhc/>.

83. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. 79,562, 79,707–08 (Nov. 14, 2016).

84. *Id.* at 79,709 (“Several commenters stated that hospitals in financial difficulty that plan to close their inpatient hospital beds will offer to transfer their HOPDs to better performing hospitals in order to ensure that critical hospital-based outpatient services are still accessible to patients in the community.”).

85. In the Final Rule, CMS interpreted section 603’s language as extending only to those off-campus hospital outpatient departments that had actually submitted a bill prior to November 2, 2015 and did not exempt outpatient departments in mid-build status. But Congress expanded the scope of section 603 in the 21st Century Cures Act to cover providers that had submitted a provider-based attestation to CMS prior to December 2, 2015. 21st Century Cures Act, Pub. L. No. 114-255, § 16001 (2016). It also extended grandfathered status to providers that could show they were in mid-build status as of November 2, 2015, by submitting a provider-based attestation by December 31, 2016, showing the provider had a binding written agreement with an outside party for the construction of the department, and including the outpatient department on the provider’s enrollment form. *Id.*

86. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. at 79,704.

that any unit number constitutes part of the address and expanding into other units would cause the department to lose its excepted status.⁸⁷ Though hospitals that need to relocate due to extraordinary circumstances (such as a natural disaster) may request permission to do so from CMS' regional offices, these circumstances do not encompass other reasons that may require an outpatient department to relocate, such as lease expiration or population shifts.⁸⁸ Certain members of Congress communicated to CMS that strict interpretation of the grandfathering provisions could make it more difficult for outpatient departments to adjust to changes in patient volume.⁸⁹

Because section 603 does not apply to on-campus facilities, hospitals may be incentivized to try to build or relocate outpatient facilities within 250 yards of the hospital to continue to receive payment under the OPPS. This shift to on-campus expansion could generate issues for patients by increasing travel times and decreasing access to care in rural and underserved areas.⁹⁰ Congress members expressed concern that this could also disadvantage hospitals that are unable to undertake on-campus expansion due to natural barriers like rivers or highways.⁹¹ Although the Final Rule also allows an exception for provider-based departments located within 250 yards of a "remote location" of a hospital (i.e., a facility owned by a hospital for the purpose of providing inpatient services),⁹² this limitation still has the potential effect of confining expansion within a 250-yard radius of a hospital's inpatient facilities.⁹³

87. *Id.*

88. *See id.* (rejecting commenters' requests to explicitly allow excepted provider-based departments to relocate without losing excepted status to provide care in an underserved area or due to loss of a lease). A hospital's ability to adapt to the needs of shifting demographics and health care needs will be vital as reimbursement methods shift to a focus on population health management. *See* Michael N. Abrams, *Toward Population Health Management*, HOSPS. & HEALTH NETWORK DAILY (July 29, 2014), <http://www.hhnmag.com/articles/4078-toward-population-health-management> (explaining that "hospitals, health care systems, and physician groups must adapt to a new world in which providers are reward for meeting quality objectives for their entire patient population" by establishing and maintaining contact with patients).

89. Letter from the United States Congress to Andrew M. Slavitt, Acting Administrator of CMS (Oct. 6, 2016), <http://strategichealthcare.net/wp-content/uploads/2016/10/101016-House-HOPD-letter-to-CMS.pdf> [hereinafter Letter to Slavitt].

90. American Hospital Association Letter, *supra* note 73, at 3. Bringing patient care closer to the population that needs the services can improve patient outcomes and overall care. MetroHealth, Comment Letter on Proposed Rule, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Sept. 6, 2016), <https://www.regulations.gov/document?D=CMS-2016-0115-1422>.

91. Letter to Slavitt, *supra* note 89.

92. 42 C.F.R. § 413.65 (2012).

93. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. at 79,708.

Some providers also stated that the strict interpretation of the relocation and transfer of ownership exceptions will make it more difficult for hospitals to acquire physician practices in their endeavor to shift from a fee-for-service system to alternative payment methods based on value instead of volume. It appears that Congress, governmental agencies, and health policy scholars intended this effect on acquisitions, however, to address their initial overarching concern that the opportunity to collect additional fees under the OPPI incentivized hospitals to acquire physicians' offices at an increased rate.⁹⁴ The consolidation among hospitals and community providers may be attributable to other factors, such as the shift toward value-based payment and increased regulatory and financial burdens experienced by independent physician practices. But the opportunity to collect additional outpatient facility fees may have provided hospitals with incentives to choose the acquisition and employment model of physician integration, instead of other methods of integration.⁹⁵ The new site-neutral payment system, however, might not achieve Congress' intent to slow consolidation as a whole.

B. Advantages

The primary advantage of the change in payment policy to off-campus hospital outpatient departments is the savings for Medicare and its beneficiaries. In 2017, CMS estimated that implementing the site-neutral policy for payments to hospital outpatient departments would save the Medicare program \$500 million in 2017 and the CBO estimated savings of \$9.3 billion over a ten-year period.⁹⁶ Ensuring that payments to

94. See *supra* Part II.B (discussing reports by MedPAC, OIG, and GAO on whether to eliminate payment differentials). See also Press Release, CMS Finalizes Hospital Outpatient Prospective Payment System Changes to Better Support Hospitals and Physicians and Improve Patient Care (Nov. 1, 2016), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-11-01.html> (calling the acquisition trend and payment differential a "long-standing concern" of Congress, MedPAC, and the OIG); Ezekiel Emanuel & Emily Gudbranson, *Our Next Administration's Health-Care Agenda*, REALCLEARPOLICY (Oct. 24, 2016), http://www.realclearpolicy.com/articles/2016/10/24/our_next_administrations_health-care_agenda.html (suggesting that Medicare can achieve savings if it reduces hospitals' incentives to acquire physician practices by implementing site-neutral payments).

95. GAO-16-189, *supra* note 5, at 11–12. The acquisition and affiliation trend among hospitals and physician groups will likely continue regardless of the changes to the OPPI due to the release of CMS' proposal implementing payment reforms under the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), which incentivizes physicians to participate in alternative payment models. See Charles R. Buck & Eric Zimmerman, *Managing the Transition to Transformation: The Strategic Implications of MACRA*, MCDERMOTT WILL & EMERY (July 6, 2016), <https://www.mwe.com/en/thought-leadership/publications/2016/07/the-strategic-implications-of-macra> ("[MACRA] will encourage physicians to consolidate into larger groups . . . or, most likely, become employed by or otherwise contractually aligned with health systems.").

96. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment

hospital-owned outpatient departments and other providers are more equalized could also help prevent the “unpleasant surprise” that Medicare beneficiaries often experience when a hospital buys their physician’s office and their coinsurance fees subsequently increase.⁹⁷

While the shift toward site-neutral payments would reduce some of the immediate financial inducements associated with vertical consolidation, it could help ensure that hospital alignment with physician practices or other providers occurs for “the right reasons,” such as increased care coordination and efficiency.⁹⁸ It may also prompt hospitals to pursue alternative forms of integration with physician groups, such as Accountable Care Organizations, which do not require vertical consolidation to succeed.⁹⁹ Incentivizing these alternative forms of integration could also reduce the traditional concerns about higher prices associated with consolidation from an antitrust and market power perspective.¹⁰⁰ Finally, these alternate models of integration could help small practices maintain independence, or even facilitate the emergence of entrepreneurial physicians that can compete with hospital outpatient departments.¹⁰¹

Section 603 also contains several limitations that seek to protect many hospitals from seeing its immediate (and arguably, detrimental) effects in the short term.¹⁰² As explained above, section 603 specifically excludes off-campus hospital outpatient departments that submitted a provider-

Systems and Quality Reporting Programs, 81 Fed. Reg. at 79,700; Virgil Dickson, *CMS Finalizes Site-Neutral Payment Rule*, MOD. HEALTHCARE (Nov. 1, 2016), <http://www.modernhealthcare.com/article/20161101/NEWS/161109982>.

97. Katz, *supra* note 1.

98. *Id.* (quoting Dr. Robert Berenson, a physician and senior fellow at the Urban Institute).

99. J. Michael McWilliams et al., *Performance Differences in Year 1 of Pioneer Accountable Care Organizations*, 372 NEW. ENG. J. MED. 1927, 1934 (May 14, 2015), <http://www.nejm.org/doi/full/10.1056/NEJMsa1414929>.

100. See Thomas L. Greaney & Douglas Ross, *Navigating Through the Fog of Vertical Merger Law: A Guide to Counselling Hospital-Physician Consolidation Under the Clayton Act*, 91 WASH. L. REV. 199, 201 (2016) (“[A]ntitrust analyses of possible vertical anticompetitive effects may be warranted based on recent evidence that some acquisitions of physicians’ practices by hospitals result in higher physician prices.”); Leigh L. Oliver & Robert F. Leibenluft, *A Mixed Bag: Sorting Out Efficiencies Arguments in Hospital Mergers*, 30 ANTITRUST 18, 18 (2015) (discussing studies that determined that integrated health systems “achieve notable efficiencies” in comparison to other studies that found that consolidation in health care leads to higher prices).

101. Robert Moffitt et al., *Analysis of the Bipartisan Budget Act of 2015*, HERITAGE FOUND. (Oct. 28, 2015), <http://www.heritage.org/research/reports/2015/10/analysis-of-the-bipartisan-budget-act-of-2015>; Kerry Young, *Medicare Plan on Hospital Outpatient Pay Draws Mixed Reviews*, CONG. Q. ROLL CALL, July 1, 2016, 2016 WL 3661377.

102. GAO-16-189, *supra* note 5, at 8 (implying that the grandfathering provisions of section 603 prevent the legislation from “fully addressing” recommendations to eliminate or reduce payment differentials).

based certification prior to December 2, 2015. Congress also ultimately extended this protection to outpatient departments that were mid-build and met certain criteria.¹⁰³ These exceptions will allow many hospital outpatient departments to continue to receive payment under the OPPTS, so long as they do not relocate or expand. Additionally, section 603 explicitly exempts services performed in an emergency department, both emergency and nonemergency. Thus, hospitals will still receive payment under the OPPTS for these services, which could help offset some of the costs associated with operating an accessible emergency department.

The Final Rule also remedied many of the concerns raised by stakeholders after the issuance of the proposed rule by eliminating both the prohibition on expansion of services and the payment model that prompted fraud and abuse concerns. As discussed in Part II, CMS ultimately decided not to adopt its proposal that sought to limit outpatient departments to providing only services within a certain clinical family to maintain its excepted status.¹⁰⁴ This may have been, in part, due to comments that suggested this would “hinder beneficiary access to innovative technologies” as well as operational issues that would have made it difficult for CMS to track which clinical services were already being performed at off-campus outpatient departments as of November 2, 2015.¹⁰⁵ Although hospitals cannot expand or relocate these outpatient departments without losing grandfathered status, the removal of the service line limitation will allow hospitals more flexibility in adjusting services to the needs of patients.

Last, many providers expressed concern regarding the additional regulatory costs and risks associated with CMS’ payment plan in the proposed rule, which would have made payments to physicians—not hospitals—for both the facility and professional costs associated with the outpatient services delivered. This proposal would have required hospitals to enter into complicated financial arrangements with the physicians to recover the hospitals’ overhead costs in delivering the services and maintaining the facility. Arrangements like these could have raised serious issues under fraud and abuse laws, such as the Anti-Kickback Statute and the Stark Law.

103. 21st Century Cures Act § 16001.

104. *Supra* Part II.B.

105. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. 79,562, 79,707 (Nov. 14, 2016). Even MedPAC agreed with commenters that the proposed “clinical family” policy could be operationally complex and pose an administrative burden to both providers and Medicare and its contractors. MedPAC recommended an alternative approach—placing an annual cap off services performed at each facility—which CMS did not adopt at this time. *Id.*

The finalized payment structure for 2017 was not accepted without question—some urged CMS to delay implementation until it could collect more data about the services provided by off-campus hospital outpatient departments.¹⁰⁶ The AHA also expressed concern that CMS had failed to properly account for differences between packaged payment under the OPDS and nonpackaged payment under the MPFS. CMS clarified in the Final Rule that it intended to use billing modifiers on hospital claims to analyze data about nonexcepted items and services to refine payment for such services over time.¹⁰⁷ Ultimately, the finalized payment structure—despite these valid concerns—established a more streamlined process for payment to hospitals that will likely be easier to manage for both Medicare and hospitals than the payment structure from the proposed rule.¹⁰⁸

CONCLUSION

CMS' refusal to delay implementation of section 603, as well as the increased proposal of site-neutral policies addressing payment discrepancies among other Medicare providers, suggest that site-neutral payment reform will continue to shape Medicare payment policy moving forward. While this shift will ultimately reduce costs to Medicare and its beneficiaries, it is too early to tell how it will affect patients' access to care or integration efforts between hospitals and physicians that are preparing for Medicare's increased focus on alternative payment models.

106. *See supra* note 66 (identifying commenters on the proposed rule who requested CMS delay implementation of the site-neutral policy for outpatient services).

107. Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. at 79,700.

108. American Hospital Association, *AHA Urges CMS to Increase Payment to Off-Campus PBDs*, AHA NEWS NOW (Dec. 21, 2016), <http://news.aha.org/article/161221-aha-urges-cms-to-increase-payment-to-offcampus-pbds>.