

SHORT-STAY, UNDER OBSERVATION, OR INPATIENT ADMISSION?—HOW CMS’ TWO MIDNIGHT RULE CREATES MORE CONFUSION & CONCERN

I. INTRODUCTION

Whether a patient should be admitted into a hospital is a difficult decision to make. Clinically, a treating physician cannot always determine with certainty whether a patient’s medical needs warrant immediate inpatient care, or if outpatient services are sufficient. Amid such uncertainty, observation care and short-stays have evolved, providing clinical flexibility for admitting physicians, while also promoting medical appropriateness for patients. Yet, under the current framework of the U.S. health care system—one held up by a reimbursement regime riddled with imbalance and drastic contrast in prices—the impact of hospital admission extends well beyond mere clinical and medical suitability.

The inter-connectedness of reimbursement and *where* a patient receives care magnifies both the importance, as well as the difficulty, in making accurate, appropriate admission decisions. Specifically, the very nature of reimbursement inherently entails competing interests, as payers, providers, and patients all sit on various sides of the health care delivery-transaction. Thus, in light of inevitable conflict, a regulatory environment in which all stakeholders are equally satisfied with where and how health care services are provided is unlikely, if not impossible. Yet recently, the regulatory climate surrounding whether a patient should be admitted into a hospital was ambiguous, confusing, and engulfed by battling interests on a clinical, financial, and operational level. Concurrently, observation care and short-stays experienced rapid and questionable growth, while patients quickly became the biggest “loser” in the transaction—facing excessive bills and denials of coverage, not knowing or understanding their medical treatment, and potentially receiving inappropriate care.

In August 2013, the Department of Health and Human Services (HHS) promulgated the Two Midnight Rule in an effort to reduce confusion surrounding the admission decision and to align conflicting interests among stakeholders. This paper argues that the Two Midnight Rule fails to establish a regulatory climate that promotes or actively works toward clarity, accuracy, or shared interests. Rather, competing concerns still fester, new perverse incentives have emerged, and, most importantly, patients have received minimal, if any, relief. The purpose of this paper is to analyze the past and

present regulatory context of inpatient admissions in order to understand and identify what changes must be made to eliminate confusion and uncertainty, and ultimately, to establish a regulatory environment in which the most *appropriate* decision can be made.

Part II provides an overview of the federal Medicare program, highlighting the regulatory history of inpatient admissions, observation care and patient status, and the focus on accuracy. Part III describes the collision of regulatory objectives and stakeholders' interests, how this circularly impacts interested parties, and, ultimately, the utilization of observation care and short-stays. Part IV outlines and analyzes the most recent regulatory action addressing patient status—the Two Midnight Rule—and discusses how stakeholders' responses suggest insufficiency and potentially new concerns. Part V recommends several changes to make under the Two Midnight Rule and also proposes an alternative solution that more effectively and appropriately addresses the admission decision and its powerful impact.

II. THE HISTORICAL REGULATORY ENVIRONMENT OF ADMITTING A PATIENT

A. *Overview of the Medicare Program*

In 1965, Title XVIII of the Social Security Act was enacted, establishing a health insurance program for the aged and disabled commonly known as Medicare.¹ The program consists of four Parts, designated as Parts A, B, C, and D. Generally speaking, Part A is hospital insurance and covers inpatient hospital stays, as well as skilled nursing facility (SNF), hospice, and some home health care, while Part B is medical insurance, covering outpatient care, preventive services, physicians' services, and medical supplies.² Part C of the Medicare Program is commonly referred to as Medicare Advantage, which provides Part A and B benefits, but through health plans offered by private health insurance companies who contract with Medicare.³ Finally, Part D provides prescription drug coverage.⁴ Parts A and B are most relevant for the scope of this paper.

The Centers for Medicare and Medicaid Services (CMS) is the authoritative arm of HHS charged with the management and oversight of the

1. 42 U.S.C. § 1395 (2012); *see generally* *Social Security History: History of SSA During the Johnson Administration 1963-1968*, SOC. SEC. ADMIN., <http://www.ssa.gov/history/ssa/lbj/medicare1.html> (last visited Jan. 4, 2014).

2. *What is Medicare?*, MEDICARE.GOV, <http://www.medicare.gov/sign-up-change-plans/decide-how-to-getmedicare/whats-medicare/what-is-medicare.html> (last visited Jan. 10, 2014).

3. *Id.*

4. Part D may be added to Original Medicare, some Medicare Cost Plans, some Medicare Private-Fee-for-Service Plans, and Medicare Medical Savings Account Plans. *Id.*

Medicare program.⁵ In its role, CMS serves as the single largest payer for health care services in the U.S.,⁶ providing coverage to as many as 52.3 million Medicare beneficiaries in 2013.⁷ As a result of its pure magnitude, CMS and the Medicare program play vital, impactful roles in the U.S. health care system for the primary reason that most health care facilities and providers would not be sufficiently profitable absent the reliable patient volume and coinciding reimbursement received from treating Medicare beneficiaries.⁸ Additionally, CMS' regulatory actions often spill over into the private sector effectively making Medicare regulations and guidance a form of precedent or industry standard in health care.⁹ Thus, although addressing the confusion surrounding the admission decision is critical in both the private and public sectors, the scope of this paper is narrowed and focuses solely on regulation of the federal Medicare program.

A critical feature of the Medicare program that has drastic regulatory implications is how it is funded. Specifically, Medicare is paid through two Trust Fund accounts held by the U.S. Department of Treasury, which are funded through payroll taxes, income taxes paid on Social Security benefits, interest earned on Trust Fund investments, and premiums for Medicare Part A.¹⁰ Accordingly, CMS and, arguably, the general public have a strong interest to guard the Medicare Trust Fund and ensure accurate payments are made, as well as prevent fraud, waste, and abuse in the Medicare program.¹¹ In recent years, the interest in protecting the Fund has been considerably heightened in response to continuously rising health care costs and, in particular, the

5. *Operating Divisions*, HHS.GOV, <http://www.hhs.gov/about/foa/opdivs/index.html> (last visited Jan. 4, 2014).

6. LISA POTERZ ET AL., *MEDICARE SPENDING AND FINANCING: A PRIMER 1* (2011), available at <http://kaiserfamilyfound.files.wordpress.com/2013/01/7731-03.pdf> [hereinafter *SPENDING AND FINANCING PRIMER*].

7. See BDS. OF TRS. OF THE FED. HOSP. INS. & FED. SUPPLEMENTARY MED. TRUST FUNDS, 2014 ANNUAL REPORT OF THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS 7 (July 28, 2014), available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/downloads/tr2014.pdf> [hereinafter 2014 TRUSTEES REPORT].

8. *SPENDING AND FINANCING PRIMER*, *supra* note 6, at 1 (“One in five dollars used to purchase health services in 2008 came through the Medicare program, which finances nearly four in ten hospital stays nationally.”).

9. See Bob Wachter, *Observation Status: How Medicare's Solution Could Make Things Worse*, KEVINMD (Aug. 11, 2013), <http://www.kevinmd.com/blog/2013/08/observation-status-medicare-solution-worse.html> (referring to CMS as “Battleship CMS” and noting when CMS turns, “it sends out giant wakes, some of which are unanticipated, even by the organization itself. Policies . . . risk capsizing a lot of boats.”).

10. *How is Medicare Funded?*, MEDICARE.GOV, <http://www.medicare.gov/about-us/how-medicare-is-funded/medicarefunding.html> (last visited Jan. 12, 2014).

11. See *infra* Part II.C (discussing the Quality Improvement Organization and various agency monitoring and review programs).

uncertainty regarding Medicare solvency and the estimates indicating bankruptcy by 2030.¹² Finally, an important regulatory characteristic of Medicare is that although it is statutorily established through the Social Security Act, the program itself is primarily administered through guidance from CMS in the form of federal regulations, administrative rules and rulings,¹³ and numerous manuals¹⁴

1. Covered Services

In its simplest form, health insurance is a contract between an insurance company and an individual (beneficiary), under which the insurer agrees to pay for all or a portion of specified medical costs when the beneficiary becomes sick or injured.¹⁵ Thus, under the Medicare program, CMS pays for specific items and services categorized into one of the four Parts (A, B, C, or D), which are rendered to treat Medicare beneficiaries.¹⁶ Yet, despite definitions for each of the four Medicare Parts, overlap and, ultimately, confusion still exist between inpatient and outpatient services. For example, many inpatient services can also be delivered in an outpatient setting, and similarly, the “diagnostic” component of the definition for outpatient services¹⁷ also satisfies the “diagnostic and therapeutic” component of the definition for inpatient services.¹⁸

12. 2014 TRUSTEES REPORT, *supra* note 7, at 7. The estimated depletion date of 2030 is a four-year increase from the previous 2013 Trustees Report’s projections. *Id.*

13. Rulings are decisions of the CMS Administrator that “serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations” *Rulings*, CMS.GOV (Feb. 27, 2012), <http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/index.html>.

14. The CMS Online Manual System offers “day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives.” *Manuals*, CMS.GOV (Nov. 5, 2013), <http://www.cms.gov/Regulationsand-Guidance/Guidance/Manuals/index.html>.

15. *Why It’s So Important To Have Health Insurance*, HEALTHCARE.GOV, <https://www.healthcare.gov/why-should-i-have-health-coverage/> (last visited Feb. 16, 2014).

16. Part A covers inpatient hospital services, which generally include (1) the furnishing of bed and board, (2) nursing and other related services, use of hospital facilities and medical social services, drugs, biologicals, supplies, appliances and equipment for use in the hospital for the care and treatment of inpatients, and (3) other diagnostic or therapeutic items or services. 42 U.S.C. § 1395(x)(b) (2012). Part B covers outpatient services, which includes diagnostic services and “other services that aid the physician in the treatment of the patient.” CTRS. FOR MEDICARE & MEDICAID SERVS., CMS PUB. NO. 100-02, MEDICARE BENEFIT POLICY MANUAL, ch. 6, § 20 (Rev. 157, June 8, 2012) [hereinafter MBPM CHAPTER 6], *available at* <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c06.pdf>.

17. MBPM CHAPTER 6, *supra* note 16, § 20.4.1.

18. 42 U.S.C. § 1395(x)(b) (2012); *see also* Jessica Gustafson & Abby Pendleton, *Billing For and Appealing Denials of Inpatient Hospital Services*, 26 HEALTH LAW. 1, 4 (Dec. 2013)

Magnifying the complexity of the Medicare program are two critical limitations regarding coverage. First, the Social Security Act prescribes that items or services that are “not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” are excluded from Parts A and B.¹⁹ Coverage is further limited to whether the item or service is “furnished in a setting appropriate to the patient’s medical needs and condition.”²⁰ Together, these restrictions serve as regulatory safeguards to ensure accurate billing of services and ultimately, to promote appropriate reimbursement.²¹

2. Reimbursement

From 1967 to 1982, both Medicare Part A and Part B were retroactively reimbursed through cost-based payments.²² After years of what federal policymakers saw as wasteful spending under the cost-based system,²³ Part A reimbursement was drastically changed in 1983 when Medicare began reimbursing inpatient services under the Inpatient Prospective Payment System (IPPS).²⁴

(highlighting the overlap and ultimate confusion between inpatient and outpatient definitions, finding them arguably “vague and circular”).

19. 42 U.S.C. § 1395y(a)(1)(A) (2012). CMS has issued guidance further describing medical reasonableness and necessity as a determination that the service is “safe and effective; not experimental or investigational . . . ; [and] appropriate, including the duration and frequency that is considered appropriate for the item or service” CTRS. FOR MEDICARE & MEDICAID SERVS., CMS PUB. NO. 100-08, MEDICARE PROGRAM INTEGRITY MANUAL, ch. 13, § 13.5.1 (Rev. 473, June 21, 2013) [hereinafter MPIM CHAPTER 13], available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf>.

20. MPIM CHAPTER 13, *supra* note 19, at ch. 13, § 13.5.1. The MPIM also defines “appropriate” to include whether the item or service is “furnished in accordance with accepted standards of medical practice . . . ; ordered and furnished by qualified personnel; one that meets, but does not exceed, the patient’s medical need; and at least as beneficial as an existing and available medically appropriate alternative.” *Id.*

21. *See infra* Part III.A.

22. DEBORAH HALE, OBSERVATION SERVICES: A GUIDE TO COMPLIANT LEVEL OF CARE DETERMINATIONS 2 (3d ed. 2011). Hospitals would submit a “cost report” including itemized expenditures the hospital incurred in the prior fiscal year. OFFICE OF INSPECTOR GEN., MEDICARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM: HOW DRG RATES ARE CALCULATED AND UPDATED 2 (Aug. 2001) [hereinafter DRG UPDATED], available at <https://oig.hhs.gov/oei/reports/oei-09-00-00200.pdf>.

23. DRG UPDATED, *supra* note 22, at 2; *see generally* Gary Claxton, *How Private Insurance Works: A Primer*, KAISER FAMILY FOUND. (April 2002), available at <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/how-private-insurance-works-a-primer-report.pdf>.

24. HALE, *supra* note 22, at 2. For additional information on the IPPS *see generally* MEDICARE LEARNING NETWORK, ACUTE CARE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM (April 2013) available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AcutePaymtSysfctsh.pdf>.

Under the IPPS, each beneficiary's case is categorized with "other clinically similar conditions into a diagnosis-related group (DRG)."²⁵ In 2007, CMS altered the methodology for calculating DRG-payments to consider the patient's level of severity.²⁶ For the purposes of this paper, a noteworthy characteristic of the DRG-payment regime is that the patient's length of stay (LOS) is not factored into the rate. Although a primary objective of this payment methodology was to decrease LOS and promote efficiency, it is critical to note that decreased LOS is not always beneficial and, under certain circumstances, actually reduces the quality of care.²⁷ As a result, the financial incentive to reduce LOS, regardless of whether a shortened stay is appropriate or beneficial, is one of the unintended consequences under the DRG-payment regime. This type of unintended consequence along with an array of similar perverse incentives have manifested under the IPPS,²⁸ subsequently leading to aggressive review of Medicare hospital claims by CMS and other agencies, in order to ensure accuracy and to protect the Medicare Trust Fund.²⁹

Reimbursement for outpatient services was similarly altered in 2000 with the implementation of the Outpatient Prospective Payment System (OPPS).³⁰ Under the OPSS, the ambulatory payment classification (APC) is the core component of the payment calculation.³¹ Each APC consists of services, clinically and resource similar, that were provided during a particular procedure,³² and hospitals may receive multiple APC-payments for a single hospital stay depending on the services furnished.³³

25. HALE, *supra* note 22, at 2.

26. Factoring in the severity ultimately provides a financial reward to hospitals taking care of the sickest patients and penalizes hospitals who effectively "cherry pick" healthy patients. *Id.* at 3.

27. WORLD HEALTH ORG., DIAGNOSIS-RELATED GROUPS IN EUROPE: MOVING TOWARDS TRANSPARENCY, EFFICIENCY AND QUALITY IN HOSPITALS 82-83 (2011) (outlining a hospital's strategy under a DRG-payment system to reduce the length of stay and inappropriately discharge early, so-called "bloody discharges," which leads to a reduction in the quality of care).

28. For a table listing the incentives of DRG-based hospital payment systems and their effects on quality and efficiency, *see id.* at 83.

29. *See supra* Part II.C (discussing the historical and current Medicare claims review programs).

30. JOHN J. SMITH ET AL., HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT UNDER MEDICARE: BACKGROUND, OVERVIEW, AND ANALYSIS 1 (May 2001), *available at* <https://www.cimit.org/news/regulatory/outpatient.pdf>.

31. *Id.* at 4.

32. *Id.*

33. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE CLAIMS PROCESSING MANUAL, CMS PUB NO. 100-04, ch. 4, § 10.2.1 (last revised Mar. 11, 2014) [hereinafter MCPM CHAPTER 4], *available at* <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf>.

A critical distinction between the DRG-payment under the IPPS and APC-payments under the OPSS is that the former is designed to reflect the cost of caring for the *average* beneficiary, while the latter is designed to reflect the cost of caring for *each* individual beneficiary and the services rendered.³⁴ As a result, providing services under Part A (inpatient) leads to considerably higher payments than if provided under Part B (outpatient). For example, in 2010, the inpatient rate under the IPPS for chest pain was \$7,600, compared to the outpatient rate under the OPSS for the same symptoms, at \$720.³⁵ In light of the overlap in definitions for inpatient and outpatient services previously discussed,³⁶ together with the drastic imbalance in payment for services to treat the same symptoms (i.e., chest pain), the financial implication of *where* the services are ultimately delivered becomes incredibly powerful.³⁷ Complicating the issue and adding considerable concern is that some studies suggest payment models and mechanisms may have significant effects on clinical decision-making.³⁸ Consequently, the role of the statutory safeguards previously discussed—medical necessity, reasonableness, and the appropriateness of the setting in which care is delivered—becomes incredibly important and not surprisingly, has created great controversy between CMS and providers.³⁹

3. Patient Payment Liability

The IPPS and OPSS represent significant imbalances not only from the perspective of providers and payers, but from patients as well. For example, as an inpatient, Part A coverage only requires the patient pay a one-time deductible⁴⁰ for all hospital services received within the first sixty days of the

34. Memorandum from the Office of Inspector Gen. on Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries 4 (July 29, 2013), available at <http://oig.hhs.gov/oei/reports/oei-02-12-00040.pdf> [hereinafter *OIG Report*].

35. See Zach Gaumer & Dan Zabinski, *Recent Growth in Hospital Observation Care*, MEDPAC 5 (Sept. 13, 2010), available at <http://www.medpac.gov/documents/september-2010-meeting-presentation-recent-growth-in-hospital-observation-care.pdf?sfvrsn=0> [hereinafter *MedPAC Recent Growth*].

36. See *supra* Part II.A.1.

37. See *infra* Part II.B (discussing the complexity and uncertainty surrounding inpatient admission).

38. See generally Joannie Shen et al., *The Effects of Payment Method on Clinical Decision-Making*, 42 MEDICAL CARE 297 (March 2004).

39. See *infra* Part III.

40. A deductible is the amount an insurance policy-holder owes for health care services covered by their insurance plan, before the insurance plan begins to cover expenses. *Deductible*, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/deductible/> (last visited Jan. 8 2014).

hospital visit.⁴¹ Conversely, as an outpatient under Part B, patients are responsible for co-payments⁴² for every service they receive and typically any self-administered drugs, which are usually not covered under Part B.⁴³ Moreover, the imbalance in payment liability on behalf of the patient augments the importance of the physician's decision on whether the patient should be admitted as an inpatient.

B. *The Admission Decision*

1. Inpatient Status

When an individual seeking care arrives at a hospital's emergency department (ED), a physician must essentially make two decisions. The first relates to what *type* of item or service is reasonable and necessary to treat the individual's sickness or injury. For example, when a patient arrives with chest pain, a physician may decide it is appropriate to furnish a bed and render diagnostic testing, nursing care, and monitoring by a nurse.⁴⁴ The second question relates to *where* the services should be rendered. Put another way, the physician must decide whether the particular situation warrants an inpatient admission.⁴⁵ Although medicine is inherently uncertain and both questions are difficult to answer with complete certainty,⁴⁶ imprecision is considerably magnified by statutory authority and CMS guidance, which suggest items or services could be rendered in *either* the inpatient or outpatient setting.⁴⁷ Thus, satisfying coverage limitations—which ensure services are medically necessary and reasonable and are rendered in a setting appropriate to the

41. CTRS. FOR MEDICARE AND MEDICAID SERVS, ARE YOU A HOSPITAL INPATIENT OR OUTPATIENT 2 (May 2014), *available at* <https://www.medicare.gov/Pubs/pdf/11435.pdf> [hereinafter INPATIENT OR OUTPATIENT].

42. A copayment is a fixed amount an insurance policy-holder pays for a covered health care service, which can vary for each type of service. *Copayment*, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/co-payment/> (last visited Jan. 8, 2014).

43. INPATIENT OR OUTPATIENT, *supra* note 41, at 2.

44. *See* Dennis M. Barry et al., *Fraud and Compliance Forum*, AM. HEALTH LAWS. ASS'N PAPERS 1 (Sept. 25, 2006), *available at* http://archive.healthlawyers.org/google/health_law_archive/program_papers2/2007_FRAUD/barry.pdf (emphasizing “there is rarely any disagreement” as to the appropriateness of furnishing the specific items and services).

45. It is critical to note that federal regulations prescribe that patients are admitted as an inpatient to a hospital “only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital.” 42 C.F.R. § 482.12(c)(2) (2014).

46. Barry, *supra* note 44, at 1-2 (concluding that the “uncertainty arises as to whether the care is medically necessary as ‘inpatient’ care or should be treated as an ‘outpatient’ observation service.”).

47. *See supra* Part I.A.1 (discussing the overlap and circular nature of the various definitions of “inpatient” found within CMS guidance and quoting the Medicare Benefit Policy Manual, which defines “inpatient” as “a person who has been admitted to a hospital for bed occupancy for the purposes of receiving inpatient hospital services.”).

patient's need and condition—transforms what initially appear to be simple questions into considerably more difficult determinations.

Complicating the matter are the various definitions and descriptions of the term “inpatient” scattered throughout multiple CMS manuals. For example, in one instance CMS describes an inpatient as “a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services,”⁴⁸ which some have described as vague and ultimately circular.⁴⁹ Similarly, another manual provides that an inpatient admission is only warranted when a patient presents with signs and symptoms severe enough that the necessary medical services and care can only be safely and effectively rendered in an inpatient setting, and “the beneficiary’s medical condition, safety, or health would be significantly and directly threatened if care was provided in a less-intensive setting.”⁵⁰ Equally as unclear is that despite the absence of a formal time-based requirement and CMS’ position that coverage is not based on the amount of time the beneficiary spends in the hospital,⁵¹ CMS instructs that for patients who are expected to need hospital care for twenty-four hours or more, admission should be ordered, and all others should be treated on an outpatient basis.⁵²

In response to the inherent uncertainty surrounding hospital admission, CMS has distinctly acknowledged, “the decision to admit a patient is a complex medical judgment that can be made only after the physician has considered a number of factors.”⁵³ Additionally, CMS manuals do not

48. CTRS. FOR MEDICARE & MEDICAID SERVS., CMS PUB NO. 100-02, MEDICARE BENEFIT POLICY MANUAL, ch. 1 § 10, (last revised Jan. 14, 2014) [hereinafter MBPM CHAPTER 1] , available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c01.pdf>

49. See Brief for American Hospital Association as Amicus Curiae Supporting Neither Party, *Bagnall v. Sebelius*, No. 3:11-CV-1703-AWT, at 4 (Nov. 19, 2012) [hereinafter AHA’s Amicus Brief] (referring to the plaintiff’s criticism of the definition of inpatient); see also Gustafson, *supra* note 18, at 4-5 (highlighting the overlap and lack of clarity in the definition of “inpatient” found throughout CMS’s multiple manuals).

50. CTRS. FOR MEDICARE & MEDICAID SERVS., CMS PUB NO. 100-08, MEDICARE PROGRAM INTEGRITY MANUAL, ch. 6 § 6.5.2(A) (last revised July 19, 2013) [hereinafter MPIM CHAPTER 6], available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c06.pdf> .

51. MBPM CHAPTER 1, *supra* note 48, § 10 (stating “admissions of particular patients are not covered or noncovered solely on the basis of the length of time the patient actually spends in the hospital.”).

52. *Id.*

53. Factors considered include: the patient’s medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital’s bylaws and admissions policies, and the relative appropriateness of treatment in each setting. Additionally, the severity of the signs and symptoms that affect the medical needs of the patient, medical predictability of something adverse happening to the patient, the need for diagnostics studies that appropriate are

reference any commercially available admissions screening criteria, such as *Milliman* or *InterQual*,⁵⁴ the absence of which supports CMS' position that the medical necessity of a hospital admission is reserved for a physician's judgment.⁵⁵ Yet, despite guidance and professional deference, the question of whether a patient should be admitted typically does not fit within such a black and white framework, as the answer is often somewhat gray and entangled with clinical uncertainty.

2. Under Observation

In the 1960s and '70s, hospital EDs began developing holding areas, which included six to ten hospital beds designated as "observation beds."⁵⁶ Patients would be sent to an observation bed if a physician encountered diagnostic problems, the diagnosis was known but the clinical course was unpredictable, or there was a general placement problem as to where the patient should receive care.⁵⁷ The rationale was that the patient's current condition did not necessarily warrant formal hospital admission, but was unstable, uncertain, and potentially serious enough to warrant close observation by medical personnel.⁵⁸ Essentially, observation care provided clinical flexibility when the answer to the admission question was somewhat gray.

At first, observational stays were included generally as a type of outpatient service. However, in 1996, in response to confusion and drastic increases in

outpatient services, and availability of diagnostic procedures at the time when and at the location where the patient presents. *Id.*

54. *Milliman* and *InterQual* are the most recognized and frequently used industry-standard admission screening criteria, which are based on medical literature and professional practice guidelines. Richard Pinson, *Documentation of Medical Necessity*, ACP HOSPITALIST (Nov. 2012), <http://www.acphospitalist.org/archives/2012/11/coding.htm> (providing several examples to demonstrate how the *InterQual* and *Milliman* criteria are used to determine inpatient medical necessity).

55. HALE, *supra* note 22, at 28; *see also* AHA's Amicus Brief, *supra* note 49, at 4 (where the American Hospital Association concludes "CMS guidance underscores the central role of the treating physician in hospital admissions" and further emphasizes that "a detailed enumeration of the circumstances in which a patient can be admitted as an inpatient would impermissibly interfere with the treating physician's medical judgment.").

56. PETER M. HILL, DIR. OF OBSERVATION SERVS., JOHN HOPKINS DEPT. OF EMERGENCY MEDICINE, HISTORY OF OBSERVATION MEDICINE 10-11 (Sept. 18, 2013) [hereinafter HILL], *available at* <https://www.mcep.org/imis15/mcepdocs/News%20Obs/13%20Hill%20History.pdf>.

57. *Id.* at 12.

58. AGENCY FOR HEALTHCARE RESEARCH & QUALITY, HCUP METHODS SERIES: OBSERVATION STATUS RELATED TO U.S. HOSPITAL RECORDS i (2002), *available at* http://www.hcup-us.ahrq.gov/reports/methods/FinalReportonObservationStatus_v2Final.pdf. Patients would be under observation for typically less than 24 hours. *Id.* It was found that placing patients "under observation" supplied health care providers with the necessary time and flexibility to make a diagnosis, absent the cost of admission. *Id.* at 5.

observation LOS,⁵⁹ CMS issued guidance to clarify observation care and its use,⁶⁰ ultimately providing that “observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital.”⁶¹ Additionally, CMS emphasizes that in most cases, the decision whether to admit a patient as an inpatient or discharge a patient from the hospital after observation services have been rendered can be made in less than forty-eight hours and is usually decided in less than twenty-four.⁶²

Although formal definitions and guidance brought clarity, observation care still generated confusion. In particular, the term “observation status” emerged and was frequently used by practitioners, health care entities, and even Medicare-affiliated organizations.⁶³ In response to the “status” characterization and concern that it created confusion and inaccurate billing and reimbursement, CMS modified its manuals in 2009 and distinctly noted that observation care is not a third type of patient status; rather, it is a type of *outpatient service*.⁶⁴ A noteworthy detail of CMS taking such a strong stance is that as an outpatient service, observation care is reimbursed under the OPPOS, which, as previously discussed,⁶⁵ typically results in lower payments than those made under the IPPS.⁶⁶ Thus, CMS’ distinct financial designation of

59. In 1994, the Prospective Payment Assessment Commission found that many observation stays should have been inpatient admissions, specifically noting some Medicare beneficiaries were under observation for days or even weeks. HALE, *supra* note 22, at 6.

60. *Id.* (quoting the 1996 CMS Medicare Hospital Manual, which stated “the purpose of observation is to determine the need for further treatment or for inpatient admission. . .due to evidence of abuse. . .observation services will be limited to a maximum of forty-eight (48) hours.”).

61. MBPM CHAPTER 6, *supra* note 16, § 20.6.

62. CMS highlights that only in “rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours.” *Id.*

63. See Ya-Ping Su, *Reducing Medically Inappropriate Admissions*, 3 MEDICARE PATIENT MGMT. 27, 31 (Jan/Feb. 2008), available at <http://www.medicarepatientmanagement.com/issues/03-01/mpmJF08-ReducingAdmissions.pdf> (stating inaccurately that “observation is a status, not a place of patient care.”).

64. See, CTRS. FOR MEDICARE & MEDICAID SERVS., CMS TRANS. 1760, MEDICARE CLAIMS PROCESSING MANUAL: CHANGE REQUEST 6492 (June 23, 2009), available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1760CP.pdf> (stating “[e]ditorial changes to the manuals remove references to ‘admission’ and ‘observation status’ in relation to observation services. . .there is no payment status called ‘observation’ . . .”).

65. See *supra* Part I.A.2 (discussing the drastic imbalance between payment under Part A (inpatient services) versus Part B (outpatient services)).

66. Hospitals can receive payment for observation services either as an hourly rate or a separate composite APC Payment. Under the first form of payment, when observation services

observation care as an outpatient service, rather than an inpatient service, underscores the perverse incentives of the reimbursement systems and ultimately the risk for inaccuracy.

C. *The Importance of Accuracy*

1. Promoting Accuracy

In order for hospitals to participate in the Medicare program and ultimately receive reimbursement from CMS, they must meet numerous statutory requirements, or Conditions of Participation (COP).⁶⁷ One significant COP is that hospitals must have a utilization review (UR) plan in place that reviews patients' claims with respect "to the medical necessity of admissions to the institution, the duration of stays, and professional services furnished."⁶⁸ If upon review, a claim for an inpatient admission is found medically inappropriate, a hospital is very limited in potentially rectifying the error. While the intricacies of CMS' policies regarding claim processing are well beyond the scope of this paper, there are two noteworthy distinctions.

First, if the inpatient admission is found medically unnecessary while the patient is still hospitalized or *before* discharge, a hospital can correct the claim and change the patient's status to outpatient by filing a Condition Code 44 (Code 44).⁶⁹ Filing a Code 44 is a time-intensive and time-sensitive process, but when accurately and fully implemented, it can provide at least some payment for services already rendered. Specifically, under a Code 44, providers can re-bill observation services as an outpatient claim and receive reimbursement under Part B.⁷⁰ Conversely, if the error is found *after* the

are ancillary and supportive to other services provided to a patient, they are often billed as an hourly, packaged service. MCPM CHAPTER 4, *supra* note 33, § 290.5.1. Under this form, counting observation hours and accurately reporting them for billing purposes has proven quite difficult for hospitals. HALE, *supra* note 22, at 12. When certain criteria are met, observation care is billed in conjunction with a high level clinic or emergency department visit, critical care services or a direct referral as an integral part of a patient's extended encounter of care and a composite APC payment is made. MCPM CHAPTER 4, *supra* note 33, § 290.5.1.

67. *Conditions for Coverage (CfCs) and Conditions of Participation (CoPs)*, CMS.GOV, https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index.html?redirect=/CFCsAndCoPs/06_Hospitals.asp (last modified Nov. 6, 2013) (describing the purpose of the conditions of participation and identifying what types of organizations must comply); *see generally* Conditions of Participation for Hospitals, 42 C.F.R. § 482 (2014) (setting forth the Conditions of Participation for Hospitals).

68. Conditions of Participation for Hospitals, 42 C.F.R. § 482 (2013).

69. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE CLAIMS PROCESSING MANUAL, ch. 1 § 50.3.2 (last revised Mar. 7, 2014) [hereinafter MCPM CHAPTER 1] *available at* <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf>.

70. *See id.* (emphasizing that hospitals can re-bill all services—including observation services—provided to the patient for the entire encounter, as long as they were "ordered by a

patient has been discharged, a hospital can file what is commonly called a “provider liable claim.”⁷¹ However, despite the available financial relief under this mechanism, it is critical to note that only certain services can be re-billed under Part B, and observation services are explicitly excluded.⁷²

2. The History of Claim Review

Despite the COP for UR and the available mechanisms for hospitals to rectify billing errors, inaccurate and potentially inappropriate claims are inevitably still submitted. Accordingly, in 1982 the Peer Review Organization (PRO) program was established,⁷³ under which the Health Care Finance Administration (HCFA), the agency authority prior to CMS, began contracting with local PROs.⁷⁴ The PROs would review and evaluate the medical necessity of inpatient claims and if the admission was ultimately found unwarranted—the patient could have been safely managed in the outpatient setting—a payment denial letter was sent to both the hospital and attending physician.⁷⁵

As a result of aggressive PRO activity, providers began using observation care—an outpatient service billed under Part B—as an arguably “safer” alternative to the overly patrolled DRG-payments under Part A.⁷⁶ Not surprisingly, using observation care as a form of relief from payment denials generated significant concern; and in 1994, the Prospective Payment Assessment Commission conducted a study that found Medicare beneficiaries were sometimes placed under observation for days or even weeks without being admitted as an inpatient.⁷⁷

physician,” as “Medicare does not permit retroactive orders or the inference of physician orders.”).

71. HALE, *supra* note 22, at 101; *see also* MCPM CHAPTER 1, *supra* note 69, § 50.3.2 (providing that when all of the criteria of Condition Code 44 are not met, one of which is that the change in patient status is made *prior to* discharge, “the hospital may submit a 12x bill type for covered ‘Part B Only’ services that were furnished to the inpatient.” (emphasis added)).

72. *See* MBPM CHAPTER 6, *supra* note 16, § 10.1 (stating that hospitals can be paid for Part B services. . .”excluding observation services. . .”). In August 2013, new billing regulations were promulgated at the same time as the Two Midnight Rule. *See generally* 78 Fed. Reg. 50,496 (Aug. 19, 2013). Yet, despite considerable changes under the new policies, observation services were *still* excluded in the Final Rule, generating strong opposition from various stakeholders. *See generally* Gustafson, *supra* note 18.

73. *See* Tax Equity and Fiscal Responsibility Act, Pub. L. No. 97-248 § 143, 96 Stat. 324, 382 (1982).

74. HALE, *supra* note 22, at 4.

75. *Id.* at 5.

76. *Id.*

77. *Id.* at 6.

3. The Claim Review Programs Today

CMS and the PROs continued to aggressively review inpatient claims throughout the 1990s and into the 2000s, and the PROs formally changed their name to the Medicare Quality Improvement Organization (QIO) in 2002.⁷⁸ Today, the QIO's mission is to "improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries,"⁷⁹ and one of its primary functions is "protecting the integrity of the Medicare Trust Fund by ensuring that Medicare pays only for services and goods that are reasonable and necessary and that are provided in the most appropriate setting."⁸⁰ CMS has established a three-pronged approach to carry out this function focusing on the following: (1) preventing improper payments before a claim is processed, (2) identifying and correcting improper payments after the claim is processed, and (3) measuring and evaluating improper payments.⁸¹

Various types of contractors are employed by CMS to implement their strategic approach and meet their goals. For example, contractors who process claims submitted by providers and make payments in accordance with Medicare rules and regulations, facilitate the "prevention" initiative.⁸² These contractors are referred to as Carriers, Fiscal Intermediaries (FIs), and Medicare Administrative Contractors (MACs).⁸³ CMS also employs contractors who identify cases of suspected fraud and take appropriate corrective actions.⁸⁴ The "measuring and evaluation" initiative is carried out through the Comprehensive Error Rate Testing (CERT) Program, which reviews small samples of claims to produce an annual error rate.⁸⁵

Finally, the "corrective" initiative is carried out through the Recovery Audit Contractor (RAC) Program, which identifies and corrects underpayments and overpayments on a post-payment basis.⁸⁶ The RAC

78. See Peer Review Organizations: Name and Other Changes – Technical Amendments, 67 Fed. Reg. 36,539, 36, 539 (May 24, 2002).

79. *Quality Improvement Organizations*, CMS.GOV, [http://www.cms.gov/Medicare/Quality Initiatives-Patient-AssessmentInstruments/QualityImprovementOrgs/index.html?redirect=/QualityImprovementOrgs](http://www.cms.gov/Medicare/Quality%20Initiatives-Patient-AssessmentInstruments/QualityImprovementOrgs/index.html?redirect=/QualityImprovementOrgs) (last modified Oct. 18, 2013, 4:44 PM).

80. *Id.*; see generally Conditions of Participation: Quality Assessment and Performance Improvement Program, 42 C.F.R. § 482.21 (2014) (setting forth the requirements of the quality assessment and performance improvement program as a condition of participation).

81. See HALE, *supra* note 22, at 56.

82. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE CLAIM REVIEW PROGRAMS: MR, NCCI EDITS, MUES, CERT, AND RAC 2 (2010) [hereinafter CLAIM REVIEW PROGRAMS], available at http://www.acponline.org/running_practice/payment_coding/medicare/med_claim_review_prog.pdf.

83. *Id.*

84. These contractors are called Program Safeguard Contractors (PSCs) and Zone Program Integrity Contractors (ZPICs). *Id.*

85. *Id.*

86. CLAIM REVIEW PROGRAMS, *supra* note 82, at 2.

Program is the product of a successful three-year demonstration project initiated in 2005, whereby over \$900 million in overpayments was collected and ultimately returned to the Medicare Trust Fund.⁸⁷ After completion of the demonstration, the program subsequently became a permanent component of CMS' oversight capacity⁸⁸ and, as a result of aggressive RAC activity, has stirred considerable controversy between providers and CMS.⁸⁹

4. The Appeals Process

Amid all of the aggressive claim review, it is critical to note that upon review and in the event of payment denial, providers and patients have a right to appeal using a five-stage process.⁹⁰ The first level includes a redetermination by a MAC, who is different from the individual who made the initial determination.⁹¹ If unsuccessful, the party can proceed to the second level with a request for reconsideration by a Qualified Independent Contractor (QIC), which allows for an independent review by a panel of physicians over the medical necessity.⁹² At the third level, after the QIC's decision, a party may request an Administrative Law Judge (ALJ) hearing, but there must be a minimum amount in controversy.⁹³ A party may request a review of the ALJ's decision by the Medicare Appeals Council at the fourth level, but here, there is no minimum claim requirement.⁹⁴ Finally, if after the Council's decision a

87. *Recovery Audit Program*, CMS.GOV, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/> (last modified Sept. 26, 2014).

88. *Id.*

89. *See supra* Part II.B.1; *see also* AHA's Amicus Brief, *supra* note 49, at 7 (discussing the controversy related to how RAC reviewers are paid, which is "on a contingent basis for collecting overpayments" and further suggesting that "[t]his payment system creates a strong financial incentive for RACs to deny claims.").

90. *See How Do I File An Appeal?*, MEDICARE.GOV, <http://www.medicare.gov/claims-and-appeals/file-an-appeal/appeals.html> (last visited Jan. 15, 2014).

91. *Original Medicare Appeals – Level 1: Redetermination By the Company That Handles Claims for Medicare*, MEDICARE.GOV, <http://www.medicare.gov/claims-and-appeals/file-an-appeal/original-medicare/original-medicare-appeals-level-1.html> (last visited Sept. 21, 2014).

92. *Original Medicare Appeals – Level 2: Reconsideration by a Qualified Independent Contractor (QIC)*, MEDICARE.GOV, <http://www.medicare.gov/claims-and-appeals/file-an-appeal/original-medicare/original-medicare-appeals-level-2.html> (last visited Sept. 21, 2014); *see also* HALE, *supra* note 22, at 160.

93. *Appeals – Level 3: Hearing Before an Administrative Law Judge (ALJ)*, MEDICARE.GOV, <http://www.medicare.gov/claims-and-appeals/file-an-appeal/appeals-level-3.html> (last visited on Sept. 21, 2014) [hereinafter *Level 3*]. The minimum amount in controversy changes each year based on the medical care component of the consumer price index. *See* HALE, *supra* note 22, at 160. For 20154, the required minimum amount is \$140.00. *Level 3, supra* note 93.

94. *Appeals – Level 4: Review By the Medicare Appeals Council (Appeals Council)*, MEDICARE.GOV, <http://www.medicare.gov/claims-and-appeals/file-an-appeal/appeals-level-4.html> (last visited Sept. 21, 2014).

specified amount is still in controversy, a party may request judicial review before a U.S. Federal District Court at the fifth and final stage of the appeals process.⁹⁵

III. REGULATION AND STAKEHOLDERS' INTERESTS COLLIDE

A. *Recent Trends in Observation Care*

1. Increased Use and LOS

In 2010, the Medicare Payment Advisory Commission (MedPAC), a Congressional agency that advises Congress on matters impacting the Medicare program,⁹⁶ held a public meeting where concern over recent growth in observation care was discussed.⁹⁷ MedPAC Commissioners presented data showing that from 2006 to 2008 Medicare outpatient observation claims grew from 900,000 to 1.1 million, roughly a twenty-six percent increase, compared to a modest 4.5 percent increase in Medicare outpatient claims overall.⁹⁸ Concern from Congress, CMS, and other interested parties greatly intensified as utilization of observation services continued to escalate. MedPAC analysts later reported that by 2011, outpatient observation visits had increased by sixty-eight percent since 2006 and during that same period, the number of Medicare inpatient admissions preceded by observation care jumped from ten (per 1,000 cases) to seventeen.⁹⁹ Similarly, a study conducted at Brown University showed that from 2007-2009 the average LOS for observation grew by seven percent, while the number of patients held in observation longer than seventy-two hours was even more significantly magnified, with an eighty-eight percent increase.¹⁰⁰

95. *Appeals – Level 5: Judicial Review By a Federal District Court*, MEDICARE.GOV, <http://www.medicare.gov/claims-and-appeals/file-an-appeal/appeals-level-5.html> (last visited Sept. 21, 2014). The minimum amount for 2014 was \$1430, which under certain circumstances, may be met by combining claims. *Id.*

96. *See About MedPAC*, MEDPAC, <http://www.medpac.gov/about.cfm> (last visited Jan. 25, 2014). MedPAC issues two reports each year, in March and June, containing recommendations to Congress based on research in the areas of economics, health policy, public health, or medicine and comments from interested parties. *Id.*

97. *Medicare Payment Advisory Committee-Public Meeting*, MEDPAC, 258 (Sept. 13, 2010), <http://www.medpac.gov/transcripts/913-914MedPACfinal.pdf>.

98. *Id.* at 263.

99. MEDPAC, JUNE 2013-DATABOOK 72 (2013), available at <http://www.medpac.gov/documents/Jun13DataBookEntireReport.pdf>. The statistics were based on Medicare hospital cost reports and outpatient claims data. *Id.*

100. *See Zhanlian Feng et al., Sharp Rise In Medicare Enrollees Being Held In Hospitals for Observation Raises Concerns About Causes and Consequences*, 31 HEALTH AFF. 1251, 1254 (June 2012). The study also found during the same period that inpatient admissions decreased. *Id.* at 1253.

2. Improper Payments

Augmenting the attention surrounding observation care was the continued and aggressive review of Medicare claims from both the RAC demonstration and permanent RAC programs.¹⁰¹ Approximately eight-five percent of the overpayments identified during the RAC demonstration were denials of inpatient, Part A claims and of those claims, forty-one percent were “wrong setting” improper payments.¹⁰² Essentially, the payments resulted from “situations where the beneficiary needed care, but did not need to be admitted to the hospital to receive that care,”¹⁰³ or put another way, services were rendered in a “medically unnecessary” setting. The permanent RAC program maintained the auditing patterns used during the demonstration and continues to focus on whether Medicare beneficiaries received services in the appropriate setting.¹⁰⁴

3. Related Issues and Variation

In response to growing concern over observation care and the high rate of improper payments, in 2013, the Office of the Inspector General (OIG) of HHS released a memorandum report comparing hospitals’ use of observation care, or “observation stays,”¹⁰⁵ with short inpatient stays.¹⁰⁶ The report examined several issues related to observation stays including: the top ten reasons, the total Medicare and beneficiary payments, the number of Part A claims that were the product of a beneficiary receiving observation services in the

101. As of May 2013, since the permanent program began in October 2009, providers had \$4.5 billion in Medicare overpayment recouped by RAC auditors. Bob Herman, *Medicare Overpayment Collection Hit \$4.5B Since 2009*, BECKER’S HOSP. CFO (May 19, 2013), <http://www.beckershospitalreview.com/racs/-/icd-9/-/icd-10/medicare-racoverpayment-collections-hit-45b-since-2009.html>.

102. CTRS. FOR MEDICARE & MEDICAID SERVS., *THE MEDICARE RECOVERY AUDIT CONTRACTOR (RAC) PROGRAM: AN EVALUATION OF THE 3-YEAR DEMONSTRATION 18-19* (June 2008) [hereinafter RAC REPORT], available at http://library.ahima.org/xpedio/groups/public/documents/government/bok1_044768.pdf.

103. *Id.*

104. AM. HOSP. ASS’N, *RACRAC: EXPLORING THE IMPACT OF THE RAC PROGRAM ON HOSPITALS NATIONWIDE 4* (Feb. 2012) [hereinafter RACRAC REPORT] (finding that “the majority of medical necessity denials reported were for 1-day stays where the care was found to have been provided in the wrong setting, not because the care was not medically necessary.”); see also AHA’s Amicus Brief, *supra* note 49, at 7. (suggesting CMS’s focus on the “wrong setting” is likely driven by financial considerations).

105. The report further broke down observation stays into observation and long outpatient stays as a result of some hospitals providing observation services without coding the claims as observation stays. See OIG Report, *supra* note 34, at 10. However for clarity, any reference to “observation stay” throughout this paper includes both observation and long outpatient stays.

106. CMS defined short inpatient stay as those lasting less than two nights. *Id.* at 3.

outpatient setting who was eventually admitted as an inpatient, and finally, how observation stays began.¹⁰⁷

Additionally, the variation in observation utilization among health care facilities was highlighted in the report. Specifically, out of the total number of short inpatient and observation stays examined, only twenty-eight percent were short inpatient. Yet, at some facilities, short inpatient stays represented only ten percent of stays, while at others seventy percent of their stays were short inpatient.¹⁰⁸ Taken together, the report demonstrates that when experiencing the same signs and symptoms, Medicare beneficiaries' fate of being admitted as inpatients or receiving services as outpatients is largely dependent upon the specific hospital at which they arrive.

B. Drivers of Utilization

The reason for significant growth in observation care is multi-faceted—increased *need of services*, *fear* as a result of competing regulatory goals and stakeholders' interests, and *misuse* as a result of general confusion. The need, fear, and misuse of observation care is driven in part by issues facing the entire health care industry, while characteristics unique to the Medicare program have also augmented recent growth and concern.

1. Need: Patient Population and Health Care Delivery

As the Baby Boomers¹⁰⁹ continue to age, the U.S. health care system faces many new challenges and demands. Specifically, a report from the American Hospital Association (AHA) projected that by 2030, six in ten Baby Boomers will be managing multiple chronic conditions,¹¹⁰ ultimately generating an increase in the demand for health care services. The likely surge in services has a particularly significant impact on CMS, whose eligibility requirements include individuals aged sixty-five years and older.¹¹¹ Thus, as the Baby Boomers enter this age bracket, the number of Medicare beneficiaries seeking

107. *See id.* at 5-8. The top ten most common reasons for observation stays in 2012 were: chest pain, digestive disorders, fainting, signs and symptoms, nutritional disorders, dizziness, irregular heartbeat, circulatory disorders, respiratory signs and symptoms and medical back problems. *Id.* at 9. Based on claim data from 2012, the majority of observation stays (78%) began as a beneficiary being treated in the ED. *Id.*

108. OIG Report, *supra* note 34, at 13-14.

109. A baby boomer is "a person who was born between 1946 and 1964. . . [This] generation makes up a substantial portion of the North American population." *Definition of 'Baby Boomer,'* INVESTOPEDIA, http://www.investopedia.com/terms/b/baby_boomer.asp (last visited Jan. 25, 2014).

110. Press Release, Alicia Mitchell, Am. Hosp. Ass'n, Baby Boomers to Challenge and Change Tomorrow's Health Care System (May 8, 2007), *available at* <http://www.aha.org/press-center/pressrel/2007/070508-pr-boomers.shtml>.

111. *What is Medicare?*, *supra* note 2.

health care services will reach epic proportions. For example, in 2012, then HHS Secretary Kathleen Sebelius noted that every day, 11,000 new Baby Boomers become eligible for Medicare, and approximately forty-eight million elderly Americans rely on the Medicare program for health insurance.¹¹²

As previously discussed, observation care is often used when physicians encounter diagnostic problems, the diagnosis was known, but the clinical course was unpredictable, or there was a general placement problem as to where the patient should receive care.¹¹³ Taken together, the upcoming surge of Medicare beneficiaries and their multiple chronic conditions suggests that treating physicians will frequently use observation care. Similarly, over the past ten years, hospitals in the U.S. have greatly struggled with ED-overcrowding.¹¹⁴ Providing ED-patients with observation services until a decision can be made as to whether they should be admitted, serves as an appealing “release valve” for overcrowded EDs, particularly if a hospital has a designated observation unit in its facility, which research suggests could also save hospitals millions of dollars annually.¹¹⁵ Moreover, both the beneficiary population and ED-overcrowding suggest the pure magnitude of individuals seeking treatment is driving the rise in observation services.

2. Fear: Competing Regulatory Objectives

As Part II of this paper demonstrates, CMS has distinctly acknowledged the difficulty in deciding whether a patient should be admitted and that making the appropriate decision requires the medical expertise and judgment of the treating physician.¹¹⁶ However, the professional and clinical deference suggested in CMS guidance is often questioned and from the providers’ perspective, ultimately trumped by various federal entities that have a strong, vested interest in protecting the Medicare Trust Fund. Most notably, CMS’ RAC program and the Department of Justice (DOJ) both intensely scrutinize Medicare claims and, arguably, a physician’s decision to admit a patient.¹¹⁷

112. Melanie Hunter, *Senior Boom: 11,000 New Seniors Become Eligible for Medicare – Every Day*, CNSNEWS (June 11, 2012), <http://cnsnews.com/news/article/senior-boom-11000-new-seniors-become-eligible-medicare-every-day>.

113. *See supra* Part I.B.2.

114. Jennifer L. Wiler, et al., *National Study of Emergency Department Observation Services*, 18 ACAD. EMERGENCY MED. 959, 961 (Sept. 2011).

115. *See* Anthony Napoli, *Emergency Department Observation Units Offer Efficiencies That Cut Costs, Improve Care*, MODERN HEALTHCARE (Nov. 1, 2014) <http://www.modernhealthcare.com/article/20141101/MAGAZINE/311019978>; Michael A. Ross et al., *Protocol-Driven Emergency Department Observation Units Offer Savings, Shorter Stays, and Reduced Admissions*, 32 HEALTH AFF. 2149, 2150 (2013), available at <http://content.healthaffairs.org.ezp.slu.edu/content/32/12/2149.full.pdf>.

116. *See supra* Part II.

117. *See supra* Part III.A; *see also infra* Part III.C.

Some stakeholders believe the heightened scrutiny ultimately impacts the admission decision, contending that a physician is less likely to admit a patient for fear of payment denials from RAC audits, or penalties from violating the False Claim Act (FCA), which is primarily enforced by DOJ-prosecutors.¹¹⁸ They argue physicians are more likely to provide observation care in the outpatient setting and bill under Part B, ultimately driving the utilization of observation services.

a. RAC Audits and Payment Denials

A RAC-audit denying a hospital's Part A claim based on an "inappropriate setting" creates considerable adverse consequences for several reasons. The most obvious reason is that hospitals ultimately relinquish a valuable DRG-payment for services *already* provided to the patient as an inpatient. Magnifying the adversarial nature of the denial is that CMS only allows payment and re-billing under Part B for some of the services already rendered.¹¹⁹ The re-billing policies ultimately provide minimal financial relief, in that ancillary services—the only re-billable or "allowable" services—typically make up only a small portion of the cost of care.¹²⁰ Thus, from the hospitals' perspective, they effectively forfeit reimbursement for services *already* rendered, based on a RAC contractor's disagreement with the treating physician's decision to admit the patient.¹²¹ The five-stage appeals process previously outlined provides an opportunity for hospitals to retrieve lost DRG-payments, or at least receive partial financial relief under Part B.¹²² However, the appeals process is time-consuming, costly, and administratively burdensome for many hospitals, ultimately serving as just another adverse alternative.¹²³ Thus, many interested parties argue the mere possibility of an

118. See AHA's Amicus Brief, *supra* note 49, at 11 (stating "fear of audits and FCA liability may be leading physicians to order observation stays instead of inpatient stays").

119. See generally MBPM CHAPTER 6, *supra* note 16, § 10; see also *supra* note 72 and accompanying text.

120. See MBPM CHAPTER 6, *supra* note 16, § 10. Ancillary services include: diagnostic tests, surgical dressings, splints and casts, outpatient physical therapy and vaccines. *Id.*

121. It is critical to note that stakeholders disagree as to whether RAC review actually increases the utilization of observation services. In a report issued by MedPAC after the 3-year RAC demonstration project, data showed that observation growth was not centered in the states participating in the demonstration, suggesting that RAC review did not make rapid growth in observation claims more likely. See *MedPAC Recent Growth*, *supra* note 35, at 12.

122. See *supra* Part II.C.3.

123. See generally Mary Agnes Carey, *Hospitals Complain to Senate Panel About Medicare Efforts on Observation Care*, KAISER HEALTH NEWS (June 26, 2013, 5:55 AM), <http://cap.sules.kaiserhealthnews.org/index.php/2013/06/hospital-officials-complain-to-senate-panel-about-medicare-efforts-on-observation-care/> [hereinafter *Hospitals Complain*] (emphasizing that although some hospitals have high success rates on appeal, the time and cost to manage RAC audits and appeals are administratively burdensome). See also *infra* Part III.C.2.

inpatient payment denial and its adverse financial impact—either through accepting the denial and losing payment, or utilizing the costly, time-consuming appeals process—is driving the increased utilization of observation services.¹²⁴

b. DOJ Prosecutors and False Claims Act Violation

The DOJ shares CMS' mission to protect the Medicare Trust Fund,¹²⁵ and although the DOJ's efforts extend well beyond billing and claims-processing, the FCA—enforced by the DOJ—is “an essential tool in the effort to crack down on fraud and abuse in Medicare” and from the providers perspective is “one of the most feared weapons against alleged fraud” as a result of its potentially devastating penalties.¹²⁶ Accordingly, if upon review, a DOJ-prosecutor disagrees with a physician's decision, finding admission unnecessary and that services should have been rendered in an outpatient setting, the claims submitted for the unnecessary inpatient stay equates to fraud against the government—a violation of the FCA.¹²⁷ The penalties for such a violation can include debilitating sanctions or, at the very worst, exclusion from participating in the Medicare program, which is considered the death knell for most hospitals.¹²⁸ As a result, the majority of health care facilities ultimately settle with the DOJ, which itself still entails considerable financial burdens.¹²⁹ Thus, as with RAC-audits, many stakeholders argue the mere risk

124. See *Observation v. Inpatient? Amid Audits, Hospitals Struggle to Decide*, THE ADVISORY BD. CO. DAILY BRIEFING (Aug. 9, 2012), <http://www.advisory.com/daily-briefing/2012/08/09/observation-v-inpatient> (noting that a risk-adverse hospital may prefer observation care in the outpatient setting, rather than admitting a patient).

125. In 1996, the Health Care Fraud and Abuse Control Program (HCFAC) was established to “combat fraud committed against health plans, both public and private.” *Health Care Fraud and Abuse Control Program Report*, OFFICE OF INSPECTOR GEN., <http://oig.hhs.gov/reports-and-publications/hcfac/index.asp> (last visited July 26, 2014). Although the HCFAC is not solely devoted to Medicare, as is the case with the RAC Program and the QIO, its efforts significantly impact the Medicare program. The HCFAC program is under the direction of both the Attorney General and the Secretary of HHS and in 2009, the DOJ and HHS created the Health Care Fraud Prevention and Enforcement Action Team (HEAT), which placed “the fight against Medicare fraud [at] a Cabinet-level priority.” *HEAT Task Force, STOP MEDICARE FRAUD*, <http://www.stopmedicarefraud.gov/aboutfraud/heattaskforce/> (last visited July 26, 2014).

126. Thomas H. Stanton, *Fraud-And-Abuse Enforcement in Medicare: Finding Middle Ground*, 20 HEALTH AFF. 28, 30 (2001).

127. AHA's Amicus Brief, *supra* note 49, at 8; see generally *The False Claims Act: A Primer*, U.S. DEPT. OF JUST., http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Primer.pdf (last visited July 26, 2014).

128. See Michael Rich, *Prosecutorial Indiscretion: Encouraging the Department of Justice to Rein in Out-of-Control Qui Tam Litigation Under the Civil False Claims Act*, 76 U. CIN. L. REV. 1233, 1252 (2008).

129. See *Fifty-Five Hospitals to Pay U.S. More Than \$34 Million to Resolve False Claims Act Allegations Related to Kyphoplasty*, U.S. DEPT. OF JUST. (July 2, 2013) <http://www.justice.gov/>

of FCA-liability for rendering “unnecessary” services in the inpatient setting and the devastating financial consequences associated with a FCA-violation are inevitably increasing the utilization of observation services.

c. Readmission Penalty Loophole

One of the core objectives of the Affordable Care Act (ACA) is to improve health care quality and patient safety,¹³⁰ and one of the programs established through the law to meet this objective is the Hospital Readmissions Reduction Program (HRRP).¹³¹ In its simplest form, the HRRP penalizes health care facilities for patients who are re-admitted to the hospital within thirty days, for the same condition as the patient’s initial admission. In 2010, the HRRP was implemented for three specific conditions, and in 2012, hospitals exceeding national re-admission rate thresholds set by CMS, were subject to penalties—a reduction in Medicare reimbursement.¹³² Accordingly, amid pressure to remain below the threshold in order to prevent penalties, observation services rendered in the outpatient setting ultimately provide hospitals with an alternative to formal inpatient admission.¹³³ Put another way, if a physician treating a patient in the ED who had previously been admitted to the hospital within the last thirty days decides to provide observation services in the outpatient setting rather than admit the patient, the hospital essentially circumvents a re-admission. Thus, various stakeholders and policymakers are concerned that observation services potentially provide a loophole to the HRRP and argue that

opa/pr/2013/July/13-civ-745.html (highlighting a total settlement of \$34 million and outlining each individual hospital’s settlement).

130. See *Strategic Goal 1: Strengthen Health Care*, HHS.GOV, <http://www.hhs.gov/strategic-plan/goal1.html> (last visited July 26, 2014).

131. See *generally Readmissions Reduction Program*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html> (last visited July 26, 2014); 42 C.F.R. §§ 412.150-54 (2014); *Medicare Hospital Readmissions Reduction Program*, HEALTH AFF. (Nov. 12, 2013), http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2013/rwjf408708 (stating that over 2,000 hospitals will forfeit more than \$280 million in Medicare funds).

132. See Jordan Rau, *Medicare to Penalize 2,217 Hospitals for Excess Readmissions*, KAISER HEALTH NEWS (Aug. 13, 2012), <http://www.kaiserhealthnews.org/stories/2012/august/13/medicare-hospitals-readmissions-penalties.aspx>.

133. See Joe Carlson, *Faulty Gauge?*, MODERN HEALTHCARE (June 8, 2013), <http://www.modernhealthcare.com/article/20130608/MAGAZINE/306089991> (stating the possible correlation between two different studies—one that demonstrated a decrease in hospital re-admissions and one that demonstrated an increase in outpatient observation—has experts concerned).

avoiding admission—or re-admission—is increasing the utilization of observation.¹³⁴

3. Misuse: Regulatory Confusion

An overarching reason, and ultimately a core driver of significant growth in observation care, is the complexity and ambiguity of the regulatory climate surrounding inpatient admission. As discussed in Part I, there is no single source of truth regarding patient status, rather guidance is scattered throughout the Social Security Act, federal regulations, administrative rulings, and multiple CMS manuals and websites.¹³⁵ Magnifying the confusion is that available definitions are often vague, circular, and at times even overlap.¹³⁶ Additionally, from a clinical point of view, many experts find CMS' designation of observation care as an outpatient service inaccurate because it implies that “all services delivered could be done in an outpatient setting. This is totally not the case, which is why observation . . . is so frustrating.”¹³⁷ Similarly, a lack of operational standards and requirements adds to the overall confusion. For example, despite the distinct types of observation care settings that exist,¹³⁸ CMS does not require facilities to have dedicated observation units or designated observation beds, and as a result, each hospital provides observation services differently—generating considerable confusion for patients, providers, and ultimately, CMS.¹³⁹

C. Impact on Stakeholders

1. Patients

Despite competing interests surrounding hospital admissions and observation care, stakeholders collectively agree that changes must be made, as this is not merely another financial feud between providers and payers. Rather,

134. See Onyinyechi Jeremiah, *A Thin Line Between Inpatient and Outpatient: Observation Status and Its Impact on the Elderly*, 20 GEO. J. ON POVERTY L. & POL'Y 141, 151-52 (Fall 2012).

135. See *supra* Part I.

136. See *e.g.*, 42 C.F.R. § 410.2 (2014) (including in the definition of outpatient “a person who has not been admitted as an inpatient”).

137. *New Medicare Guidelines Do Not Solve Problems of ‘Observation’ Patients*, UNIV. OF WIS. SCH. OF MED. & PUB. HEALTH (Feb. 20, 2014), <http://www.med.wisc.edu/news-events/new-medicare-guidelines-do-not-solve-problems-of-observation-patients/42874> (quoting Dr. Ann Sheehy).

138. See Ross et al., *supra* note 115, at 2150 (setting forth a table that outlines the “[h]ospital [s]ettings [i]n [w]hich [o]bservation [s]ervices [a]re [p]rovided.”).

139. Brian Contos, *The Expanding Role of Observation Services: Q&A with Brian Contos*, THE ADVISORY BD. CO. (April 29, 2011, 9:26 AM), <http://www.advisory.com/Research/Cardiovascular-Roundtable/Cardiovascular-Rounds/2011/04/The-Expanding-Role-of-Observation-Services-Q-A-with-Brian-Contos> [hereinafter Contos].

patients and families are often “unwitting victims [and] collateral damage” amid all of the confusion.¹⁴⁰ In the late 2000s, numerous stories from frustrated, confused patients emerged, detailing alarming medical bills beneficiaries were forced to pay as a result of receiving observation care as an outpatient, rather than an inpatient.¹⁴¹ The bills included charges for medications not covered in the outpatient setting under Part B, as well as multiple unexpected patient co-payments.¹⁴² Augmenting the concern and confusion was that prior to receiving the outpatient medical bill, many beneficiaries mistakenly thought they had been admitted to the hospital and had received observation care as an inpatient.¹⁴³

In addition to direct financial consequences, the inpatient-outpatient status distinction can also indirectly harm beneficiaries. For example, in order to be eligible for SNF coverage under Part A, a Medicare beneficiary must attain a “qualifying inpatient hospital stay,” which means the beneficiary has been a hospital inpatient for at least three consecutive days.¹⁴⁴ Yet, observation care—as an outpatient service—does not count towards the required three inpatient days.¹⁴⁵ As a result, numerous Medicare beneficiaries have paid thousands of dollars in SNF bills because they mistakenly believed their observation stays counted towards a “qualifying inpatient hospital stay,”¹⁴⁶ and some have even been forced to simply go without needed care.¹⁴⁷

After growing frustration from patients, families, and various stakeholders, in November of 2011, the Center for Medicare Advocacy Group and National Senior Citizens Law Center filed a class action lawsuit on behalf of seven Medicare beneficiaries¹⁴⁸ alleging among other things that “by allowing

140. Wachter, *supra* note 9.

141. See, e.g., Susan Jaffe, *Patients Held for Observation Can Face Steep Drug Bills*, USATODAY (May 1, 2012, 3:31 PM), <http://usatoday30.usatoday.com/money/industries/health/drugs/story/2012-04-30/drugs-can-be-expensive-in-observation-care/54646378/1> [hereinafter *Steep Drug Bills*].

142. *Id.*

143. See, e.g., Ina Jaffe, *For Hospital Patients, Observation Status Can Prove Costly*, NAT'L PUB. RADIO (Sept. 4, 2013, 3:40 AM), <http://www.npr.org/blogs/health/2013/09/04/218633011/for-hospital-patients-observation-status-can-prove-costly>.

144. INPATIENT OR OUTPATIENT, *supra* note 41, at 4.

145. *Id.*

146. See Alex Nixon, *Observation Stays Don't Count for Medicare Coverage, Many Seniors Harshly Learn*, TRIBLIVE: BUSINESS (Aug. 24, 2013, 9:00 PM), <http://triblive.com/business/headlines/4532564-74/observation-medicare-hospital#axzz2uxVH6Vgd>.

147. *CMS Addresses Observation Status Again. . . And Again, No Help for Beneficiaries*, CTR. FOR MEDICARE ADVOC., <http://www.medicareadvocacy.org/cms-addresses-observation-status-again-and-again-no-help-for-beneficiaries/> (last visited Feb. 18, 2014) (highlighting that “[p]atients who cannot afford to pay privately for their SNF stay. . . may forego needed post-acute care in a SNF. . .”).

148. See *Bagnall v. Sebelius*, No. 3:11CV1703, 2013 WL 5346659 (D. Conn. Sept. 23, 2013).

observation status, a billing mechanism, to deprive intended beneficiaries of Part A coverage,” CMS violates the Medicare statute and “the purpose of Medicare, which is to provide coverage for hospitalization and for follow-up SNF care.”¹⁴⁹ The claim was ultimately dismissed, but as of the date of this writing, plaintiffs appealed the issue of “the right to effective notice and review procedure for beneficiaries placed on observation status” and in late 2014, began arguing their case.¹⁵⁰ Two years after the initial lawsuit, the “Improving Access to Medicare Coverage Act of 2013” bill was introduced to amend the Social Security Act and apply outpatient observation services toward a “qualifying inpatient hospital stay.”¹⁵¹ Although the house-bill garnered 162 co-sponsors, it ultimately did not make it through the 2013-2014 Congressional session.¹⁵²

2. Providers

The aggressive RAC-reviews and payment denials have generated significant administrative and financial burdens for hospitals. For example, one hospital, a 285-bed facility, spent approximately 8,600 hours and \$240,000 in 2013 to sufficiently manage RAC-audits and appeals internally.¹⁵³ Another health care organization needed to add twenty-two full-time employees just to properly meet the demands of the RAC program.¹⁵⁴ Similarly, the intense reviews and denials have led many hospitals to utilize the appeals process. According to data collected by the AHA, in 2012, hospitals appealed more than forty percent of RAC-denials and won over seventy percent of the time.¹⁵⁵ However, despite success on appeal, many hospitals find the entire appeals process overly burdensome and frustrating, and some legislators have urged

149. *Bagnall v. Sebelius*, No. 3:11CV1703, 2013 WL 5346659, at *5 (D. Conn. Sept. 23, 2013); *Press Release: Class Action Lawsuit Filed Against Federal Government to Improve Access to Medicare Coverage*, CTR. FOR MEDICARE ADVOC., (Nov. 3, 2011) <http://www.medicareadvocacy.org/press-release-class-action-lawsuit-filed-against-federal-government-to-improve-access-to-medicare-coverage/>.

150. *Bagnall v. Sebelius* 3:11CV1703 at *25; *see also Bagnall v. Sebelius*, CTR. FOR MEDICARE ADVOC. (Nov. 12, 2014), <http://www.medicareadvocacy.org/bagnall-v-sebelius-no-11-1703-d-conn-filed-november-3-2011/> (providing a summary and overview of the history and current status of the lawsuit). On October 23, 2014, the case was argued on appeal. *Id.*

151. Improving Access to Medicare Coverage Act, H.R. 1179, 113th Cong. (2013) [hereinafter *Improving Access Bill*] available at <https://www.congress.gov/113/bills/hr1179/BILLS-113hr1179ih.pdf>.

152. *See* H.R. 1179, GOVTRACK.US, <https://www.govtrack.us/congress/bills/113/hr1179#overview> (last visited Feb. 21, 2015).

153. *Hospitals Complain*, *supra* note 123, at 23.

154. *Id.*

155. Bob Herman, *AHA: Hospitals Successfully Appeal 72% of Medicare RAC Denials*, BECKER'S HOSP. CFO (June 5, 2013), <http://www.beckershospitalreview.com/finance/aha-hospitals-successfully-appeal-72-of-medicare-rac-denials.html>.

CMS to consider “the balance between program integrity and administrative burden.”¹⁵⁶

By the fall of 2014, providers were not the only ones overwhelmed and frustrated with Medicare appeals. Specifically, amid an eighteen-month backlog of over 800,000 cases, which many legislators described as an “unacceptable high,” in August 2014, CMS offered a settlement to certain hospitals willing to resolve their appeals in exchange for partial payment.¹⁵⁷ The terms of the agreement took an “all-or-nothing” approach where CMS would pay hospitals and health systems sixty-eight percent of the net payable amount of their claims sitting in the Agency’s backlog, in exchange for withdrawing all of their pending appeals.¹⁵⁸ The settlement offer generated mixed responses from stakeholders, with some finding it a “helpful sign to providers that the Agency is recognizing that the appeals process is simply not a workable and fair way to deal with these issues,” and others emphasizing it “fails to address the underlying cause of the problem—overzealous RAC-reviewers.”¹⁵⁹

IV. CMS RESPONDS: THE TWO-MIDNIGHT RULE

In response to the confusion and abuse, growing frustration from providers, and negative financial impact on beneficiaries, in May of 2013, CMS issued a proposed rule to address the problems surrounding inpatient admission.¹⁶⁰ The proposed rule, commonly referred to as the Two Midnight Rule, was subsequently finalized in August of that same year with minimal revision and ultimately became part of the 2014 IPPS Final Rule (Final Rule).¹⁶¹ Concurrently, CMS issued a proposed rule relating to Part B Inpatient Billing,¹⁶² which also ultimately became part of the Final Rule. As Part III of this paper demonstrated, billing plays a critical role in the problems surrounding inpatient admission and also serves as a powerful driver of the

156. *Hospitals Complain*, *supra* note 123, at 23.

157. Bob Herman, *Why One Congressman Wants to Scrap Medicare’s Hospital Appeals Deal*, MODERN HEALTHCARE (Sept. 19, 2014) <http://www.modernhealthcare.com/article/20140919/BLOG/309199996/why-one-congressman-wants-to-scrap-medicares-hospital-appeals-deal>.

158. CTRS. FOR MEDICARE & MEDICAID SERVS, FREQUENTLY ASKED QUESTIONS-HOSPITAL APPEALS SETTLEMENT FOR FEE-FOR-SERVICE DENIALS BASED ON PATIENT STATUS REVIEWS FOR ADMISSIONS PRIOR TO OCTOBER 1, 2013, at 1 (Sept. 16, 2014) [hereinafter CMS FAQ-SETTLEMENT], available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/Hospital_Appeals_SettlementFAQs_9162014_508.pdf.

159. Michael D. Williamson, *CMS Offers Partial Payment in Bid to Trim Number of Hospital Patient Status Appeals*, 23 HEALTH LAW REP., 1196 (Sept. 11, 2014).

160. *See generally* 78 Fed. Reg. 27,486 (proposed May 10, 2013).

161. *See generally* 78 Fed. Reg. 50,85 (Aug. 19, 2013) [hereinafter Two-Midnight Rule].

162. *See generally* 78 Fed. Reg. 16,614 (proposed Mar. 18, 2013).

growth in observation services. However, the intricacies of the final billing rule, as well as the profound response from stakeholders, generated enough legal and policy analysis worthy of a separate discussion beyond the scope of this paper.¹⁶³ Thus, Part IV provides an overview and analysis of the Two Midnight Rule and highlights the response from stakeholders, which ultimately suggests insufficiency and new concern.

A. Overview of the Two-Midnight Rule

Generally speaking, the Two Midnight Rule clarifies the admission criteria for hospital inpatient services, as well as the review criteria for payment purposes under Medicare Part A.¹⁶⁴ The Rule additionally includes specific requirements relating to physician orders, physician certification, and medical record documentation.¹⁶⁵

1. Medical Necessity of Inpatient Admission

Under the Two Midnight Rule, an inpatient admission will be deemed generally appropriate and services rendered will be covered by CMS under Part A when “the physician expects the beneficiary to require care that crosses two midnights and admits the beneficiary to the hospital based upon that expectation,” or the patient is receiving services on the Inpatient Only List.¹⁶⁶ As in prior guidance, CMS continues to emphasize the complexity of the admission decision and contends the Rule does not “override the clinical judgment of the physician,”¹⁶⁷ acknowledging there will be rare and unusual circumstances that justify an inpatient admission expected to span less than two midnights.¹⁶⁸ However, CMS concludes that except in cases involving inpatient-only services or a rare and unusual exception, “if the physician expects to keep the beneficiary in the hospital for only a limited period of time

163. See generally Gustafson, *supra* note 18, at 5 (discussing the insufficiency of the final billing rule).

164. Two-Midnight Rule, *supra* note 161, at 50,506.

165. See generally *id.* at 50,938-943; see also CTRS. FOR MEDICARE AND MEDICAID SERVS, HOSPITAL INPATIENT ADMISSION ORDER AND CERTIFICATION (Jan. 2014), available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/IP-Certification-and-Order-01-30-14.pdf> [hereinafter ORDER AND CERTIFICATION].

166. Two-Midnight Rule, *supra* note 161, at 50,944.

167. *Id.* at 50,946.

168. *Id.* CMS instructs that “rare and unusual circumstances” will be further detailed in sub-regulatory instruction. *Id.* See generally CTRS. FOR MEDICARE & MEDICAID SERVS, FREQUENTLY ASKED QUESTIONS-2 MIDNIGHT INPATIENT ADMISSION GUIDANCE AND PATIENT STATUS REVIEWS FOR ADMISSIONS ON OR AFTER OCTOBER 1, 2013, at 11 (Mar.12, 2014) [hereinafter CMS FAQ-2 MIDNIGHT], available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/Questions_andAnswersRelatingtoPatientStatusReviewsforPosting_31214.pdf.

that does not cross two midnights, the services would be generally inappropriate.”¹⁶⁹

2. Review of Inpatient Admission

In addition to clarifying the criteria for inpatient admission, the Two Midnight Rule modifies and essentially establishes two policies for contractors reviewing admissions for payment purposes. The policies include (1) the Two Midnight *Presumption* and (2) the Two Midnight *Benchmark*.¹⁷⁰

a. Two Midnight Presumption

Under the presumption policy, CMS has expressed that review efforts will *not* focus on inpatient hospital claims with a LOS that spans greater than two midnights, as such claims will be presumed generally appropriate for Part A payment—absent evidence of systematic gaming, abuse, or delays in providing treatment with the intent to meet the two-midnight requirement.¹⁷¹

b. Two Midnight Benchmark

Conversely, under the benchmark policy, CMS specifically directs review efforts to focus on inpatient hospital claims with a LOS that only spans one midnight or less,¹⁷² as the inpatient status for such claims is not presumed reasonable and necessary for payment purposes. Under the policy, reviewers are to determine the “appropriateness of [the] inpatient admission versus treatment on an outpatient basis.”¹⁷³ CMS instructs reviewers to evaluate the hospital’s compliance with the (1) admission order requirements, (2) certification requirements, and (3) the two-midnight benchmark.¹⁷⁴

The first two evaluation criteria relate to and assess specific new requirements added by the Final Rule. For example, under the Rule, a formal admission order is now required to initiate an inpatient hospitalization.¹⁷⁵ The

169. Two-Midnight Rule, *supra* note 161, at 50,944.

170. *Id.* at 50,949.

171. *Id.*

172. *Id.*

173. CTRS. FOR MEDICARE & MEDICAID SERVS, REVIEWING HOSPITAL CLAIMS FOR PATIENT STATUS: ADMISSION ON OR AFTER OCTOBER 1, 2013 at 1 (Mar. 12, 2014), available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/ReviewingHospitalClaimsforAdmissionforPosting03122014.pdf> [hereinafter REVIEWING HOSPITAL CLAIMS].

174. *Id.*

175. Two-Midnight Rule, *supra* note 161, at 50,942 (providing that “inpatient status only applies prospectively, starting from the time the patient is *formally admitted* pursuant to a physician order for inpatient admission.”) (emphasis added). See also Gustafson, *supra* note 18, at 5 (discussing CMS’s prior guidance, whereby a formal order was not required for admission).

order must be written¹⁷⁶ and made by either a physician or “other practitioner.”¹⁷⁷ Although the explicit term “inpatient” need not be in a valid order, CMS believes it is in the best interest of the hospital that the practitioner use language that “clearly expresses intent to admit the patient.”¹⁷⁸ Additionally, certification is now a COP under Part A coverage.¹⁷⁹ Thus, upon review, verification of the practitioner order and physician certification serves as evidence of the medical reasonableness and necessity of inpatient services.

The third evaluation criterion addresses the two-midnight benchmark for which supportive documentation in the medical record is critical.¹⁸⁰ Meeting the two-midnight benchmark is based on whether “it was reasonable for the physician to expect the beneficiary to require a stay lasting two midnights and that expectation is documented in the medical record.”¹⁸¹ CMS acknowledges the difficulty of such a question and provides

“if a physician is uncertain whether a patient will be discharged after one midnight or whether the beneficiary will require a second midnight of care, the initial day should be spent in observation until it is clearly expected that a second midnight would be required, at which time the physician may order admission.”¹⁸²

Further, CMS provides that when a physician is determining whether an inpatient admission meets the two-midnight benchmark and thus, an admission is warranted, the time spent receiving outpatient services—including observation services—may be considered.¹⁸³

176. Two-Midnight Rule, *supra* note 161, at 50,941 (concluding a “verbal order is a temporary administrative convenience for the physician and hospital staff but it is not a substitute for a properly documented and authenticated order for inpatient admission.”). *See also* ORDER AND CERTIFICATION, *supra* note 165, at 5.

177. ORDER AND CERTIFICATION, *supra* note 165, at 4. Other practitioner” or “ordering practitioner” is defined as one “who is: (a) licensed by the state to admit patients to hospitals, (b) granted privileges by the hospital to admit inpatients to that specific facility, and (c) knowledgeable about the patient’s hospital course, medical plan of care, current condition at the time of admission.” *Id.*

178. *Id.* at 6.

179. 78 Fed. Reg. at 50,969 (stating that “Medicare Part A pays for inpatient hospital services. . .only if a physician certifies. . .”). CMS requires the physician certification to include specific information, such as authentication of the practitioner order, reason for inpatient services, the estimated time required in the hospital and plans for post-hospital care. ORDER AND CERTIFICATION, *supra* note 165, at 1.

180. Eric Fontana, *The Two-midnight Rule: What You Need to Know*, THE ADVISORY BD. CO. (Oct. 15, 2013), <http://www.advisory.com/research/cardiovascular-roundtable/cardiovascular-rounds/2013/10/q-a-the-two-midnight-rule>.

181. Two-Midnight Rule, *supra* note 161, at 50,950.

182. CMS FAQ-2 MIDNIGHT, *supra* note 168, at 14.

183. Two-Midnight Rule, *supra* note 161, at 50,952.

Reviewers are directed to apply the benchmark in a similar manner¹⁸⁴ and further instructed to consider “complex medical factors that support a reasonable expectation of the needed duration of the stay relative to the two-midnight benchmark.”¹⁸⁵ Finally, upon review, the “trigger” for the two-midnight timeframe is when the beneficiary starts receiving diagnostic or therapeutic services following arrival at the hospital.¹⁸⁶

B. Analysis of the Two-Midnight Rule

Both hospital and physician leaders argue the Two Midnight Rule “undermines medical judgment and disregards the level of care actually needed to safely treat a patient.”¹⁸⁷ This paper supports this argument and further contends that establishing a presumption and using time-based criteria led to such an effect, as well as other adverse consequences.

1. Presumption of Reasonableness and Unreasonableness

Under the Two Midnight Rule, by establishing a presumption of reasonableness for inpatient stays spanning more than two-midnights, a presumption of *unreasonableness* for stays spanning less than two-midnights is concurrently established. Thus, despite CMS’ continued acknowledgment that the admission decision is complex and requires the medical judgment of a physician,¹⁸⁸ the two-midnight presumption simultaneously supports and contradicts CMS’ position. Whether or not such an effect was intended remains unclear. However, the impact of this result is significantly magnified where CMS specifically directs claim-reviewers to focus evaluation on inpatient admissions spanning less than two-midnights.¹⁸⁹ In response, physicians argue that under the Two-Midnight Rule “they are presumed to

184. *Id.* CMS states that “where a physician’s expectation that an inpatient stay will surpass two-midnights is reasonable and well documented, the benchmark may be applied to incorporate all the time in which the patient received care in the hospital.” *Id.*

185. *Id.* at 50,949. The complex factors in CMS’s guidance include “beneficiary medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk (probability) of an adverse event occurring during the time period for which hospitalization is considered.” REVIEWING HOSPITAL CLAIMS, *supra* note 173, at 4.

186. REVIEWING HOSPITAL CLAIMS, *supra* note 173, at 5. CMS has specifically directed reviewers to exclude triaging activities. *Id.*

187. Letter from the Am. Hosp. Ass’n and the Am. Med. Ass’n to Marilyn Tavenner, Adm’r, Ctrs. for Medicare & Medicaid Servs 1 (Nov. 8, 2013), available at <http://www.aha.org/letters/2013?&p=4>.

188. See generally REVIEWING HOSPITAL CLAIMS, *supra* note 173.

189. 78 Fed. Reg. at 47, 949 (stating that “CMS’ medical review efforts will focus on inpatient hospital admissions with lengths of stay crossing only one midnight or less after admission.”).

have made an error and provided medically unneeded care if an inpatient doesn't spend two midnights in a hospital bed."¹⁹⁰

In order to overcome a presumption of unreasonableness, physicians must provide sufficient documentation in the patient's medical record, supporting their prior expectation that the patient required medically necessary services that would span two-midnights.¹⁹¹ CMS maintains its longstanding position that reviewing the reasonableness of the inpatient admission decision should be based on the "information known to the physician at the time of admission."¹⁹² Yet, CMS also provides that "the *entire* [emphasis added] medical record may be reviewed to support or refute the reasonableness of the decision."¹⁹³ By expanding the scope of review, CMS significantly jeopardizes the reviewer's objective evaluation of the physician's decision, which was based on and restricted to *only* information at the time of admission. CMS further provides that "entries after the point of the admission order are only used in the context of interpreting what the physician knew and expected at the time of the admission."¹⁹⁴ However, the difficulty in making such a restrictive interpretation—in hindsight—and having the benefit of the patient's actual LOS and final outcome, considerably threatens a fair review and significantly undermines the physician's medical judgment and expectation—both of which did not reap the benefits of hindsight.

Similarly, even with admission decisions that qualify for the two-midnight presumption of reasonableness, a physician's medical judgment is still threatened, as the presumption does not eliminate all forms of review.¹⁹⁵ In the Final Rule, CMS acknowledges, "it was not our intent to suggest that a two-midnight stay was presumptive evidence that the stay at the hospital was necessary; rather, only that *if* [emphasis added] the stay was necessary, it was

190. Joe Carlson, *CMS Delays Two Midnight Rule Until After Sept. 30*, MODERN HEALTHCARE (Jan. 31, 2014), <http://www.modernhealthcare.com/article/20140131/NEWS/301319944> [hereinafter *CMS Delays Till September*].

191. See REVIEWING HOSPITAL CLAIMS, *supra* note 173, at 4.

192. *Id.*

193. *Id.*

194. *Id.*

195. Contractors can still review claims that satisfy the presumption in order to: (1) ensure the medical necessity of rendered services, (2) ensure medical necessity of hospitalization, (3) verify provider coding and documentation requirements, (4) comply with CERT review, and (5) comply with CMS or other entities need for review. Gustafson, *supra* note 18, at 12-13 (noting that although "contractors will not focus medical review efforts on claims satisfying the 2-midnight presumption for the purposes of determining whether inpatient status was appropriate. . . claims may nonetheless be reviewed. . ."). See also *Inpatient Hospital Review*, CMS.GOV, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/InpatientHospitalReviews.html> (last updated May 12, 2014) [hereinafter *Hospital Review*] (stating MACs "will continue other types of inpatient hospital reviews. . .").

appropriately provided as an inpatient stay.”¹⁹⁶ The focus of review has arguably simply shifted from *appropriate setting* under prior guidance to *medical necessity* under the Two Midnight Rule.¹⁹⁷ As one form of scrutiny is not better than the other, a presumption of reasonableness ultimately provides little protection for physicians, whose medical judgment is still faced with continued questioning and undermining review.

2. Time-Based Criteria

As discussed in Part II, prior guidance included *consideration* of whether a patient was expected to stay twenty-four hours. Yet, the Two Midnight Rule represents a distinct regulatory shift from clinical to time-based criteria. CMS intended the shift to provide clarity to the admission decision. However, time-based criteria, or put another way, considering the LOS when determining the appropriateness of an inpatient admission, generate new forms of patient confusion and clinical concern, while also promoting perverse incentives.

Under the Two Midnight Rule, CMS clearly states their policy “is not contingent upon the level of care required,”¹⁹⁸ rather it is based upon whether a physician expects the patient’s LOS to span at least two midnights. From the patient’s perspective, this will likely be confusing and frustrating. For example, under extreme circumstances, a patient could be in the Intensive Care Unit (ICU) for as long as forty-seven hours receiving high-level care and yet still not be formally admitted to the hospital if the stay does not ultimately cross two midnights. Equally concerning is that clinicians have expressed apprehension in considering LOS, as it does not “reliably differentiate patient populations that merit different insurance coverage.”¹⁹⁹ CMS offers potential relief by conceding there are “rare and unusual” circumstances where admission would be appropriate without an expectation of a two midnight hospital stay.²⁰⁰ However, just how rare and unusual circumstances must be—from CMS’ perspective—is still unclear. As of the date of this writing, only *one* such rarity has been identified,²⁰¹ highlighting CMS’ continued focus on time rather than severity and ultimately demonstrating the Agency’s disregard for the level of care required to safely treat a patient.

196. Two-Midnight Rule, *supra* note 161, at 50,951.

197. See Wachter, *supra* note 9 (noting there is “widespread panic that, rather than soothing the RAC auditors, the new policy will be fresh meat for them.”).

198. Two-Midnight Rule, *supra* note 161, at 50,946.

199. Ann M. Sheehy, et al., *Observation and Inpatient Status: Clinical Impact of the 2-Midnight Rule*, 9 J. OF HOSP. MED. 203, 208 (Feb. 14, 2014) [hereinafter *Clinical Impact of Rule*].

200. See REVIEWING HOSPITAL CLAIMS, *supra* note 173, at 3-4; see also Two-Midnight Rule, *supra* note 161, at 50,946.

201. An exception to the general rule whereby admission is reasonable without an expectation of a stay lasting two midnights is a beneficiary with newly initiated mechanical ventilation support. See CMS FAQ-2 MIDNIGHT, *supra* note 168, at 11.

Additionally, CMS acknowledges there may be situations in which the beneficiary improves faster than the physician reasonably expected.²⁰² Yet, from the physician's perspective, justification of such situations entails burdensome documentation requirements and inevitably leads to intense review. Thus, extending a patient's LOS to span two-midnights—in order to qualify for the attached presumption and effectively circumvent scrutiny—will likely serve as an appealing approach for providers.

CMS addresses this temptation by repeatedly referring to section 1862(a)(1) of the Social Security Act, which prohibits payment for services that are not “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”²⁰³ Further, reviewers are instructed to “exclude extensive delays in the provision of medically necessary services from the two midnight benchmark . . . and to monitor inpatient hospital claims spanning two or more midnights . . . for evidence of systematic gaming, abuse, or delays . . .”²⁰⁴ There is valid concern over the likely temptation to increase, potentially inappropriately, a patient's LOS under the Two Midnight Rule. Thus, heightened scrutiny by CMS and reviewers is warranted. Yet, when taken together—imposing a time-based benchmark while simultaneously prohibiting delay—the Two Midnight Rule ultimately resembles a regulatory game of cat and mouse.²⁰⁵

C. Response from Stakeholders

CMS explained that the Two Midnight Rule “responds to both hospital calls for more guidance about when a beneficiary is appropriately treated—and paid by Medicare—as an inpatient, and beneficiaries' concerns about increasingly long stays as outpatients due to hospital uncertainties about payment.”²⁰⁶ The following two sections highlight how the Two Midnight Rule insufficiently responds to patients' and hospitals' calls for help and how it arguably creates more confusion and concern. One health care leader noted “[i]t's rare to have hospital and nursing home administrators, physicians and patient advocates all agreeing about a Medicare policy, but in this case 'there's unanimity of dislike.’”²⁰⁷

202. *Id.* at 13.

203. See Two-Midnight Rule, *supra* note 161, at 50,948, 50,954.

204. REVIEWING HOSPITAL CLAIMS, *supra* note 173, at 6-7.

205. See Wachter, *supra* note 9 (predicting the “unproductive and maddening cat-and-mouse game will continue. . .”).

206. *Hospital Review*, *supra* note 195.

207. Paula Span, *Two Kinds of Hospital Patients: Admitted, and Not*, N.Y. TIMES (Oct. 29, 2013), http://newoldage.blogs.nytimes.com/2013/10/29/two-kinds-of-hospital-patients-admitted-and-not/?_php=true&_type=blogs&_r=0 [hereinafter *Two Kinds of Patients*] (quoting Carol Levine, director of the Families and Health Care Project of the United Hospital Fund).

1. Patients

Despite the vigorous opposition from patient advocacy groups, strong media attention, and noteworthy litigation discussed in Part III, the Final Rule does not eliminate or even modify the three-day statutory requirement for SNF-coverage. Thus, a Medicare beneficiary is still required to achieve a “qualifying inpatient hospital stay”—three consecutive days as an inpatient—before CMS will cover services subsequently rendered in a SNF.²⁰⁸ Additionally, CMS still does not *require* hospitals to tell a patient whether they have been admitted. Rather the Agency has included on its website²⁰⁹ and patient-handout²¹⁰ the following statement: “Remember: Even if you stay overnight in a regular hospital bed, you might be an outpatient. Ask the doctor or hospital.”²¹¹ Finally, the Two Midnight Rule fails to address or ameliorate the high co-payments beneficiaries face under Part B when treated as an outpatient under observation, as well as the lack of drug coverage.²¹² Thus, from the beneficiaries’ point of view, the Two Midnight Rule provides minimal if any financial relief.

2. Providers

The Two Midnight Rule received vigorous opposition from providers relating to financial, legal, and operational concerns. First, CMS estimates that under the Two Midnight Rule, more patients will be classified as inpatient and thus, inpatient expenditures will increase by about \$220 million.²¹³ As a result, in the Final Rule, CMS proposed a 0.2% reduction in hospital payments to

208. See *Your Medicare Coverage—Skilled Nursing Facility (SNF) Care*, MEDICARE.GOV, <http://www.medicare.gov/coverage/skilled-nursing-facility-care.html#2956> (last visited May 12, 2014) [hereinafter *SNF Coverage*]. CMS created the *Your Medicare Coverage—Skilled Nursing Facility (SNF) Care* website after promulgating the Two Midnight Rule. The website explicitly states “your doctor may order observation services to help decide whether you need to be admitted to the hospital as an inpatient or can be discharged. During the time you’re getting observation services in the hospital, you’re considered an outpatient—you can’t count this time towards the 3-day inpatient hospital stay needed for Medicare to cover your SNF stay”. *Id.*

209. See *SNF Coverage*, *supra* note 208.

210. See INPATIENT OR OUTPATIENT, *supra* note 41.

211. However, several months after the Two Midnight Rule was finalized, the state of New York, frustrated and dissatisfied with CMS’s response, passed legislation that requires written and oral notification within 24 hours of being put on observation. See 2013 N.Y. Sess. Laws S. 3926-A (McKinney); see also Susan Jaffe, *Fighting ‘Observation’ Status*, N.Y. TIMES (Jan. 10, 2014), <http://newoldage.blogs.nytimes.com/2014/01/10/fighting-observation-status/> (noting that failure to do notify the patient under NY law could result in penalties as high as \$5000).

212. Carol Levine, senior director at the John Hopkins Hospital noted, “[i]f you cross two midnights, you’re and inpatient. If not, you’re a pumpkin’...and being a pumpkin can cost patients a lot of money”, calling the Two Midnight Rule the Cinderella Rule. *Two Kinds of Patients*, *supra* note 207.

213. Two-Midnight Rule, *supra* note 161, at 50,507-08.

offset the increased admissions resulting from the new admission and review criteria.²¹⁴ The proposed payment reduction generated vigorous opposition from providers, leading to multiple lawsuits from numerous health care organizations.²¹⁵ The AHA, along with several national health care systems,²¹⁶ filed a lawsuit, which AHA's General Counsel stated, "is a necessary first step to challenge the entire two-midnight policy."²¹⁷ Allegations include "the 0.2 Percent Payment Cut is arbitrary and capricious because CMS relied on indefensible assumptions in adopting the policy."²¹⁸ Additionally, hospitals argue the reduction is invalid because CMS failed to comply with notice and comment procedures required by the Administrative Procedure Act.²¹⁹ As of the date of this writing, lawsuits related to CMS' proposed payment reduction are pending litigation.²²⁰

Magnifying concern are recent studies projecting just the opposite of CMS' estimations under the Final Rule—an increase in observation, rather than an increase in admissions²²¹—and early experience dealing with the Rule has even further supported these projections. For example, in May 2014, the Senior Director of Clinical Resource Management at John Hopkins Medical System in Baltimore stated that since October 2013 (just two months after the Rule was finalized) they had seen a "three-fold increase in the number of patients [their] physicians cautiously predicted would only stay one midnight, and thus began as outpatients, but later had to admit for longer stays."²²² Similarly, in the fall of 2014, the Cleveland Clinic reported a 4.7% decline in

214. *Id.* at 50,507.

215. *See Hospitals Plan Three-Pronged Attack on the Two-Midnight Rule*, THE DAILY BRIEFING-THE ADVISORY BD. CO. (Jan. 27, 2014), <http://www.advisory.com/daily-briefing/2014/01/27/hospitals-plan-three-pronged-attack-on-the-two-midnight-rule>.

216. Plaintiffs included: Banner Health, Mount Sinai Hospital, Einstein Healthcare Network, Wake Forest Baptist Medical Center, Greater New York Hospital Association, Healthcare Association of New York, New Jersey Hospital Association, and Hospital and Healthsystem Association of Pennsylvania. Complaint, *Am. Hosp. Ass'n et al. v. Sebelius*, Case 1:14-cv-00607 (D. D.C. April 14, 2014) (last updated Dec. 19, 2014).

217. Eric Topor, *AHA Appeal Brief Challenges Hospital Rate Cut, Asks for Expedited Review*, 18 BNA'S HEALTH CARE FRAUD REP. 135, 140 (Feb. 19, 2014) (noting that AHA's request for expedited judicial review was appropriate because it related to a pure question of law regarding the payment reduction, which AHA further alleged is beyond the Provider Reimbursement Review Board's authority).

218. *See* Complaint, *supra* note 216, at 22.

219. *Id.* at 23.

220. *See, e.g., id.*

221. *Clinical Impact of Rule*, *supra* note 199, at 203.

222. Susan Jaffe, *Medicare May Be Overpaying Hospitals for Short-Stay Patients*, KAISER HEALTH NEWS (May 20, 2014), <http://www.kaiserhealthnews.org/Stories/2014/May/20/medicare-observation-care-overpaying-hospitals-for-short-stays.aspx> [hereinafter *Medicare Overpaying*].

inpatient admissions, while observation-stays spiked 17.9%.²²³ Thus, although implementation of the Two Midnight Rule has been quite difficult, as will be further discussed below, and its actual impact on admissions remains unclear, initial responses seem to bolster claims against the reasonableness of CMS' proposed reimbursement reductions.

A second reason providers adamantly oppose the Two Midnight Rule is the complexity and confusion surrounding its implementation. As previously discussed in Part III, RAC-audits and payment denials have a devastating impact on hospitals and as health care organizations became increasingly more confused and unsure how to implement the new Rule, looming RAC-reviews—demanding accuracy—pose a significant threat. In response to outcry from providers and one hundred members of Congress asking for postponement, CMS partially delayed enforcement of the Rule, originally set to begin October 2013, for ninety days.²²⁴ Specifically, CMS delayed RAC-auditor scrutiny of claims and established the “Inpatient Hospital Prepayment Review ‘Probe & Educate’” review process.²²⁵ Under the review process, MACs²²⁶ are instructed to conduct reviews of pre-payment patient status claims using a “probe and educate strategy,” where a MAC (1) selects a sample of ten claims at a hospital (twenty-five for large hospitals) for pre-payment review and (2) conducts education outreach efforts based on the results of the sample reviews and repeats where necessary.²²⁷

Despite the delay of post-payment review and the development of the Probe and Educate Period, frustration and confusion from providers continued and CMS delayed RAC-scrutiny for a *second* time, extending the Probe and

223. Beth Kutscher, *Cleveland Clinic Sees Lower Margin and Volume, Higher Expenses*, MODERN HEALTHCARE (Aug. 18, 2014), <http://www.modernhealthcare.com/article/20140818/NEWS/308189961/cleveland-clinic-sees-lower-margin-and-volume-higher-expenses>.

224. Joe Carlson, *More than 100 House Members ask CMS to Delay ‘Two Midnight’ Rule*, MODERN HEALTHCARE (Sept. 24, 2013), <http://www.modernhealthcare.com/article/20130924/NEWS/309249944> (highlighting the strong opposition towards the rule just days before it was supposed to go into effect).

225. Hanna Jaquith, *Waving the White Flag? CMS Offers Hospitals Amnesty for ‘Two-Midnight’ Rule*, DAILY BRIEFING BLOG – THE ADVISORY BD. CO. (Sept. 30, 2013), <http://www.advisory.com/daily-briefing/blog/2013/09/cms-offers-amnesty-on-two-midnight-rule>. See also *Hospital Review*, *supra* note 195.

226. See *supra* Part I.C (explaining the purpose of Medicare Administrative Contractors (MACs)).

227. *Hospital Review*, *supra* note 195. On February 24, 2014, CMS published a document with examples and explanations of why claims have been denied during the “probe and educate” process, so far. See *Medicare Inpatient Hospital Probe and Educate Status Update*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 24, 2014) <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/UpdateOnProbeEducateProcessForPosting02242014.pdf>.

Educate Period until September 30, 2014.²²⁸ However, shortly after the second delay, in April 2014, Congress passed the Protecting Access to Medicare Act,²²⁹ which extends both the Probe and Educate Period as well as the delay of RAC-review for a *third* time.²³⁰ Accordingly, as of the date of this writing, MACs are permitted to conduct pre-payment review under the Probe and Educate process for admissions after October 1, 2013 through March 31, 2015, while RACs are prohibited from conducting post-payment review of claims during this time.²³¹

V. SUGGESTIONS FOR THE FUTURE

A. *Changes Under the Two-Midnight Rule*

Despite strong opposition from providers and dissatisfaction from patients and families, as of the date of this writing, CMS maintains its position and the Two Midnight Rule still stands.²³² Accordingly, Part V of this paper presents changes that can be made to provide patients with financial relief, promote equitable insurance coverage, and ease operational implementation.

1. Introduce Caps on Co-payments and Provide Drug Coverage

As demonstrated multiple times throughout this paper, the financial strain on patients under Part B coverage versus Part A is quite significant. To help alleviate the burden, CMS should cap the total amount of out-of-pocket co-payments for which a beneficiary may be liable at the inpatient deductible

228. *CMS Delays Till September*, *supra* note 190.

229. *See generally* Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, 128 Stat. 1040.

230. *Id.* § 111.

231. *Hospital Review*, *supra* note 195.

232. In May 2014, CMS Deputy Administrator told lawmakers “CMS was considering a new system for defining and paying for short hospital stays. . . suggesting the agency could get rid of or alter the two-midnight policy”. *Officials Are Seeking Input for an Alternative Payment System for Short Stays*, THE DAILY BRIEFING – THE ADVISORY BD. CO. (May 21, 2015), <http://www.advisory.com/daily-briefing/2014/05/21/modern-health-care-cms-signals-it-might-ditch-the-two-midnight-rule>. *See also* Joe Carlson, *CMS Considering Alternatives to ‘Two-Midnight’ Rule*, MODERN HEALTH CARE (May 20, 2014), <http://www.modernhealthcare.com/article/20140520/NEWS/305209965>. Several months later, on September 12, 2014 during a MedPAC public meeting, MedPAC staff specifically addressed the issue of hospital short-stays. Presenters highlighted the controversy stirring among stakeholders by the Two Midnight Rule and requested commissioners to provide feedback and research direction on policy changes that could be explored. *See* Zach Gaumer, Kim Neuman & Craig Lisk, *Hospital Short Stay Policy Issues*, MEDPAC (Sept. 12, 2014), *available at* <http://www.medpac.gov/documents/september-2014-meeting-presentation-hospital-short-stay-policy-issues.pdf?sfvrsn=0>.

amount under Part A.²³³ At the very least, if beneficiaries continue to be inappropriately designated as outpatients because of confusion, or to avoid payment denials, this change would prevent out-of-pocket expenses (excluding medications) under Part B from costing the patient more than an inpatient admission.²³⁴ Additionally, CMS should expand Part B coverage to include self-administered medications commonly used in the delivery of observation care. Current regulations require beneficiaries to pay for itemized drugs administered while under observation, which often results in significant additional costs for the beneficiary. For example, in 2013, Missouri Medicare beneficiaries were billed eighteen dollars for one baby aspirin administered while under observation,²³⁵ and similarly, one hospital charged seventy-one dollars for a blood pressure pill that typically costs sixteen cents at a local pharmacy.²³⁶ Although expanding coverage to include such medications would notably increase costs for CMS, as a large insurer, the Agency has considerable leverage in negotiating lower drug prices and would ultimately bare a far lesser financial burden than beneficiaries. At the very least, CMS should expand coverage to include drugs typically used to treat the ten most common conditions²³⁷ for which beneficiaries receive observation care.

2. Apply Observation Care *Prior to Admission* Towards the “Qualifying Inpatient Hospital Stay”

Part III of this paper discussed the “qualifying inpatient hospital stay” requirement—three consecutive inpatient days—that beneficiaries must attain before receiving SNF coverage, and Part IV reiterated CMS’ strong position that observation services do not count towards the requirement. As of the date of this writing, several Medicare demonstrations are currently underway to assess whether the “qualifying inpatient hospital stay” should stay in place.²³⁸ Similarly, although it did not make it through the most recent Congressional session, bipartisan legislation that applies all observation services rendered to the beneficiary towards a “qualifying inpatient hospital stay” was recently proposed.²³⁹ Both the demonstrations and proposed bill would provide

233. Christopher W. Baugh, et al., *Observation Care—High-Value Care or a Cost-Shifting Loophole?*, 369 NEW ENG. J. MED. 302, 305 (July 25, 2013).

234. *Id.*

235. *Steep Drug Bills*, *supra* note 141.

236. *Id.*

237. See OIG Report, *supra* note 34, at 19 (listing the ten most common conditions).

238. See Susan Jaffe, *Medicare Testing Payment Options That Could End Observation Care Penalties*, KAISER HEALTH NEWS, July 22, 2014, <http://www.kaiserhealthnews.org/Stories/2014/July/22/Medicare-testing-payment-options-that-could-end-observation-care-penalties.aspx> (discussing various experiments such as the Medicare Pioneer ACO program, as well as Medicare Advantage plans of which 95% of plans waived the requirement for their 12 million members).

239. See Improving Access Bill, *supra* note 151.

considerable financial relief to beneficiaries and promote equitable insurance coverage. However, it is critical to note that CMS' "qualifying inpatient hospital stay" is an important safety mechanism to help ensure services are medically necessary and provided in the most appropriate setting. Thus, eliminating the three-day requirement may generate perverse incentives, such as premature discharge from the hospital, or inappropriate and unwarranted treatment at a SNF. Similarly, until the delivery of observation care is appropriately standardized and can be consistently evaluated through protocol adherence and quality metrics, CMS should not apply all observation services, as suggested in the proposed legislation. However, current regulations remain inequitable.

A more reasonable alternative to current regulations, as well as the demonstrations and proposed legislation, is to apply only observation services rendered *before* inpatient admission to the "qualifying inpatient hospital stay." This is not only clinically and equitably reasonable, but it also appropriately aligns with CMS' position under the Two Midnight Rule, where claim reviewers are instructed to consider the "time the beneficiary spent receiving outpatient services within the hospital prior to inpatient admission. . . such as observation services" when evaluating inpatient claims.²⁴⁰ Thus, similar consideration should be made to determine satisfaction of the "qualifying inpatient hospital stay."²⁴¹

3. Use an Hourly-Based Benchmark

As demonstrated in Part IV, aggressively focusing on LOS when determining whether to admit a patient ultimately leads to confusion, clinical concern, and perverse incentives. Additionally, although many hospitals are open 24-hours a day, 7-days a week, 365-days a year, the operation of health care facilities today does not efficiently or equitably align with a two-midnight benchmark, particularly one that yields the power to dictate an individual's insurance coverage.²⁴² In one recent study, patients placed in observation

240. REVIEWING HOSPITAL CLAIMS, *supra* note 173, at 5.

241. Many stakeholders urge CMS to eliminate the "qualifying hospital stay" requirement all together. The Affordable Care Act allows CMS to waive the requirement and in May 2014, the agency granted pioneer Accountable Care Organizations and bundled payment demonstrations flexibility to waive the requirement. A deputy administrator at CMS has emphasized that the results of such waivers will be closely evaluated. *See Medicare Overpaying*, *supra* note 222.

242. For example, if patient X arrives at the emergency department (ED) on Tuesday night at 11:58 pm complaining of chest pain, is immediately admitted and subsequently gets discharged on Thursday morning, patient X's admission will be presumed reasonable and medically necessary and services will be covered under Part A without any copayments. Compared to patient Y who arrives at the same ED, complains of the same pain, is immediately admitted and receives the same services, and is discharged after the same amount of time, but Patient Y arrives 5 minutes later than Patient X, at 12:03 Wednesday morning. Under the Two Midnight Rule,

earlier in the day were less likely to meet the two-midnight benchmark than those later in the day, suggesting that utilizing a full day to render services—as a result of resource availability, staffing, and scheduling—is ultimately “harmful” to attaining inpatient status.²⁴³ Thus, under the Two Midnight Rule, a patient’s insurance coverage, and ultimately their financial liability, could be largely determined by operational factors over which the patient and sometimes the hospital have no control.

If the admission decision under the Two Midnight Rule continues to hinge upon time-based criteria, CMS should use an hourly-based benchmark, rather than midnight-based. Although an hourly benchmark will not entirely eliminate implementation challenges or the perverse temptation to extend LOS, the change would generate consistency, reduce confusion, and provide more equitable insurance coverage.

B. *Beyond Midnight*

Even if the suggested changes were made, the Two Midnight Rule still demands a level of certainty that is difficult, if not impossible, to attain in today’s clinical environment and ultimately perpetuates a regulatory game of cat and mouse between CMS and providers. This paper suggests CMS establish a *separate* payment that attaches to an intermediary patient status. This would narrow financial gaps and provide relief from financial pressures, ease the difficulty in the admission decision, mitigate perverse incentives, and eventually reduce both the desire and need for constant review. Most importantly, it would create a regulatory and clinical environment where the most *appropriate* decision can be made.

1. Short-Stay Payment Adjustment and Status Designation

Historically and under the Two Midnight Rule, CMS’ regulatory solutions have focused on re-defining inpatient status, ultimately trying to make it more distinct and discernable from outpatient. However, striving for such strict black-and-white distinction only exacerbates the difficulty in making a decision that inevitably entails a gray answer. Additionally, having such imbalanced yet incredibly powerful reimbursement attach to each status not only magnifies the significance of the admission decision, but also generates the need and desire for relentless review. Therefore, CMS should establish a

admitting Patient Y is not medically reasonable and payment under Part A would be inappropriate. Thus, Patient Y is an outpatient and services are covered under Part B, which imposes co-payments, does not provide drug coverage and does not count towards the three-day requirement for SNF coverage—as a result of arriving five minutes later. *Two Kinds of Patients*, *supra* note 207.

243. See *Clinical Impact of Rule*, *supra* note 199, at 208.

short-stay inpatient payment that attaches to a short-stay or intermediary patient status.

If a short-stay inpatient payment were developed, time-based criterion would not dictate the admission decision. Rather, similar to CMS guidance prior to the Two Midnight Rule,²⁴⁴ physicians would be instructed to simply consider general timeframes. For example, if a patient was expected to need services for less than twenty-four hours, they should be treated as an outpatient, while if they were expected to need services for longer than forty-eight hours they should be admitted as an inpatient. If it was unclear whether the patient would need services for longer than twenty-four hours, the patient should be admitted as a “short-stay” patient, where they would receive medically necessary inpatient services to treat their current condition and any additional services needed to further determine their status.

Reimbursement for traditional inpatient and outpatient stays would remain the same, but a short-stay inpatient visit would be reimbursed using an adjusted DRG-payment. An adjusted short-stay DRG-payment, or “SS-DRG”, would reflect a reduced percentage of the full DRG-payment for each condition and would intentionally be at or near Part B payment for outpatient observation services that treat the same condition. Low reimbursement would mitigate perverse incentives to place patients in short-stay status when outpatient is sufficient or more appropriate. However, as an incentive to utilize short-stay status, reviewers would be instructed to *only* consider services received under short-stay status when determining whether an inpatient admission was reasonable and medically necessary. Thus, although there is no presumption of reasonableness attached to short-stay status, receiving short-stay care *prior* to inpatient admission mitigates the risk of payment denial upon review. Put another way, a short-stay status almost serves as a “gatekeeper” to admission for patients whose immediate status was uncertain. Additionally, if a patient were subsequently admitted as an inpatient after being treated under short-stay status, the SS-DRG-payment would be adjusted on a sliding scale to reflect the full DRG-payment.

The purpose and ultimate goal of the short-stay status is to foster the concept of *temporary* care—a temporary status in which health care providers are *actively* monitoring and treating the patient to determine where they need to go. By having a low reimbursement rate, providers will be incented to keep patients moving to the next appropriate level of care, and yet, the inherent reasonableness of the short-stay environment and the way in which services are delivered, affords protection from payment denials and reduces the need and desire for relentless review.

244. See *supra* Part II.

VI. CONCLUSION

The challenges surrounding the admission decision will likely endure, so long as providing health care services and treating patients remain chained to inadequate reimbursement methods that are riddled with perverse incentives and imbalance. Until then—without a single solution that equally pleases all stakeholders—competing interests must *align*. Claim reviews must be done to find errors and promote accuracy, not perpetuate fear and instigate cat and mouse behavior. Decisions must be made based on what is clinically appropriate for the patient, not on what payment is least likely to be denied or will provide the highest return. The Two Midnight Rule does not take the necessary steps toward creating a regulatory environment where this can occur. Yet, amid strong, collective stakeholder interest to find a better solution, changes can be made and alternatives explored so the most appropriate decision can be made.

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