Physicians working in hospitals are often called upon to make a hard decision: is admission the best course of treatment for a patient, or would the better course be to treat him or her as an outpatient, observing the patient’s condition? Medicare’s guidance to hospitals says that this question requires physicians to exercise “complex medical judgment” after looking at many clinical factors. Yet, the decision can have financial consequences not only to the physician and hospital, but to the beneficiary as well. For PPS hospitals, the DRG payment received for an admission goes farther toward covering the resources needed to provide services to the patient as compared to outpatient reimbursement. For beneficiaries, being placed in observation can negatively affect Medicare coverage for self-administered drugs and their eligibility for skilled nursing facility (SNF) benefits after discharge.

Now, more than ever before, reviewers are looking over the shoulder of the physicians making these decisions. According to CMS’s recently issued FY 2011 RAC report to Congress, RACs are actively reviewing (and denying) short stay inpatient hospital admissions.¹ According to CMS’s report, short stay admissions “represent a large portion of the [$797.4 million] FY 2011 overpayment collections” identified by RACs.² Medicare guidelines expressly state that the length of stay is not determinative of the medical necessity of an inpatient admission, but the fact is that Medicare contractors, as well as the HHS Office of Inspector General and the Department of Justice, are targeting short stay admissions.

² Id.
Hospitals are reporting increases in the number of inpatient denials for lack of medical necessity, along with information showing that nearly three-quarters of these denials are reversed when appealed. The HHS Office of Inspector General recently released a report describing ALJ reversal rates in Part A appeals that are consistent with these reports. CMS reports a lower reversal rate for RAC denials that are subsequently appealed. But even still, the volume of reversals is troublesome because it suggests that hospitals are incurring expenses to appeal a large number of denials that should never have been made. But more fundamentally, the data raise questions about the RAC process and the standards that RACs are using to conduct their medical reviews. Are their review standards consistent with Medicare’s guidance to hospitals? Do they appropriately consider physician judgment? In many cases, RACs deny short stay inpatient claims on the basis that the services could have been provided on an outpatient basis, including findings that the admission merely constituted observation services. CMS, however, will not allow hospitals to rebill for the full range of outpatient services, including observation services, following the denial of an inpatient stay. This is the case even when it is undisputed that such services were medically necessary. But the Medicare Appeals Council, Medicare’s chief administrative tribunal, reads the rules differently and has ordered CMS to pay for these services, including observation services.

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5 FY 2011 RAC report at 10. This report cites a reversal rate of 43.6 percent for all claims that are appealed, but the report has major flaws that understate the number of inpatient claim denials reversed on appeal. The report compares data on appeals filed in 2011 to appeals decided in 2011. But there is a lengthy time lag between an initial claim denial and a decision by an ALJ. Therefore, many (if not most) of the claims denied by RACs and appealed in 2011 -- the year in which CMS states RACs began to focus on short stays -- would not be decided by ALJs until 2012 or even later. The results of those appeals would not appear in this report. The statistic is further distorted by the fact that the number of filed appeals in 2011 -- again, when short stay reviews increased significantly -- vastly outnumber the volume of appeals decided in 2011.
In the most recent Outpatient Prospective Payment Final Rule (FY 2013), CMS stated that it had “heard from various stakeholders that hospitals appear to be responding to the financial risk of admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review by electing to treat beneficiaries as outpatients receiving observations services . . .”6 CMS noted that the number of cases of Medicare beneficiaries receiving observation services for more than 48 hours has increased from 3 percent in 2006 to approximately 7.6 percent in 2010.7

Beneficiary advocates have now challenged CMS’s observation services policy in court. The American Hospital Association and some hospitals have challenged CMS’s limited rebilling policies. And there are legitimate concerns that RAC medical necessity reviews of inpatient stays are overly restrictive. Amidst all of this, CMS has recently signaled through various actions that the agency is considering policy changes in these areas.

This outline is organized to provide the legal background to understand the many issues that are raised by this problem and to assess any policy changes that CMS might undertake in this area.

This outline will cover:

1. Medicare’s guidance regarding inpatient status and admission criteria, including both the guidance set forth in Medicare manuals as well as the criteria that contractors actually apply on medical review;
2. Medicare’s guidance regarding inpatient status changes, including the guidance that CMS relies upon to restrict Part A to Part B rebilling, such as Condition Code 44;
3. Medicare’s guidance regarding observation services, what they are and how they are paid;
4. A summary of the American Hospital Association v. Sebelius litigation;
5. A summary of Bagnall v. Sebelius, the beneficiary class action challenging CMS’s observation status policy; and

7 Id.
Recent CMS responses to these problems.

I. Medicare Guidance On Inpatient Admission Standards

Medicare’s published guidance for inpatient admission is non-specific and directs physicians to exercise their “complex medical judgment.” But in contrast with this deference to physician judgment, CMS also directs contractor medical reviewers to use “screening tools” while at the same time exercise their own clinical judgment as to whether the service was medically necessary based upon information in the record. The reported number of inpatient admission denials that are reversed on appeal raises questions as to the criteria RAC medical reviewers are following when reviewing inpatient admissions.

A. What is an Inpatient?

1. Medicare defines an inpatient as “a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services.” Medicare considers a person to be an inpatient if the person is “formally admitted as an inpatient with the expectation that he or she will remain at least overnight and occupy a bed . . . ”

2. Once admitted, the person is considered an inpatient for Medicare purposes “even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight.” Thus, Medicare guidance does not require that a patient stay overnight for the admission to be medically necessary.

3. Medicare conditions of participation require “the recommendation” of a physician (or licensed practitioner permitted by state law to admit) for inpatient admissions.

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8 Benefit Policy Manual (BPM) (CMS Pub. 100-02), ch. 1, § 10.
9 Id.
10 Id.
11 42 C.F.R. § 482.12(c)(2); Claims Processing Manual (CPM) (CMS Pub. 100-04), ch. 1, § 50.3.1.
4. Under CMS’s manuals, “[t]he physician or other practitioner responsible for a patient’s care at the hospital is also responsible for whether the patient should be admitted as an inpatient.”

B. Inpatient Admission Criteria

1. Medicare does not set forth case-by-case, specific standards to guide physicians and hospitals as to when Medicare will cover inpatient admissions, such as designating by symptoms or diagnosis when a hospital admission will be considered to be medically necessary.

2. Instead, Medicare guidance relies upon the medical judgment of the admitting physician. Specifically, this guidance states that the decision to admit is a “complex medical judgment which can be made only after the physician has considered a number of factors . . . .”

3. Medicare’s Benefit Policy Manual directs physicians to use a 24-hour period as a benchmark for exercising their judgment: “they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis.”

4. Medicare directs physicians to look at “the patient’s medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital’s by-laws and admissions policies, and the relative appropriateness of treatment in each setting.” CMS further provides that other factors the physician should consider when making the decision to admit include:

- the severity of the signs and symptoms exhibited by the patient;
- the medical predictability of something adverse happening to the patient;
- the need for diagnostic studies that appropriately are outpatient services; and
- the availability of diagnostic procedures at the time when and at the location where the patient presents.

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12 BPM (CMS Pub. 100-02), ch. 1, § 10.
13 BPM (CMS Pub. 100-02), ch. 1, § 10.
14 Id.
15 Id.
16 Id.
C. Contractor Criteria Used to Review Admission Decisions

1. CMS’s Program Integrity Manual instructs contract medical reviewers that “[i]npatient care rather than outpatient care is required only if the beneficiary’s medical condition, or health would be significantly and directly threatened if care was provided in a less intensive setting.”17 “The beneficiary must demonstrate signs and/or symptoms severe enough to warrant the need for medical care and must receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis.”18 To the extent that the Program Integrity Manual sets forth more strict criteria than the Benefits Policy Manual, the Medicare Appeals Council is of the view that the Benefits Policy Manual controls. The Council has stated that, “[i]n the absence of statutes, regulations, or binding coverage policies that set forth specific criteria for inpatient hospital admissions, the Council has long held that the [Benefits Policy Manual], Chapter 1, Section 10 inpatient hospitalization provisions are to be applied to decide coverage of inpatient hospital admissions.”19

2. CMS’s Benefits Policy Manual states that medical reviewers must only consider the medical evidence that was available to the physician at the time he or she made the admission decision. They are instructed not to take into account other information, such as test results, that was not available to the admitting physician unless it would support the admission decision.20

3. CMS requires that its contractors use a “screening tool” as part of their medical necessity reviews of inpatient hospital claims, though CMS does not mandate that any particular criteria be used.21 According to CMS, “in addition to screening instruments, the reviewer applies his/her own clinical judgment to make a medical review determination based on documentation in the medical record.”22 Thus, this provision recognizes that contractors are not required to deny claims that fail “screening tools” and such admissions may still be medically necessary based upon application of medical judgment.23 The reversal rate for RAC inpatient denials raises questions about how RACs are using screening criteria.

4. Commonly used “screening” criteria include InterQual Clinical Decision Support (published by the McKesson Corporation) and the Milliman Care

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17 Program Integrity Manual (PIM), (CMS Pub. 100-08), ch. 6, § 6.5.2.A.
18 Id. at § 6.5.2.
20 BPM (CMS 100-02), ch. 1, § 10.
21 PIM (CMS 100-08), ch. 6, § 6.5.1 (“The reviewer shall use a screening tool as part of their medical review of acute IPPS.”) (emphasis added).
22 Id.
23 See also Guidance on Hospital Inpatient Admission, MLN Matters SE 1037 at 2.
Guidelines (published by Milliman, Inc.). Literature associated with screening instruments, like InterQual, state that they are to be used for screening purposes only, and are not intended to be used to make final clinical or payment determinations.

5. In a 2009 Medicare Appeals Council (MAC) decision, InterQual was described as “widely used” among acute care hospitals and certain CMS contractors. The MAC gave “substantial deference” to a decision to admit that passed InterQual screening criteria.24

6. In the FY 2013 Final OPPS rule, CMS stated that it received comments both supporting and opposing a change in policy that would apply more specific criteria for inpatient admission than that found in current manuals. Some commenters opposed more specific criteria on the basis that it would eliminate the role of physician medical judgment.25

II. Medicare Rules Regarding Changes in Patient Status, including Billing Rules

Patient status (whether a patient is considered to be an inpatient or an outpatient) and the timing of that decision have significant Medicare coverage and payment implications for providers and beneficiaries.26 Specifically, CMS requires providers to change a patient’s status according to the requirements for the use of Condition Code 44 in order to bill Part B for medically necessary services provided during the course of an inpatient stay. This policy essentially prohibits rebilling Part B if an inpatient stay was denied. The Medicare Appeals Council, however, takes the opposite view and has concluded on many occasions that CMS’s payment and billing rules allow hospitals to receive Part B payment for the full range of medically necessary hospital services provided (and payable under Part B) if Part A payment is denied (see infra, Section IV).

Because status changes require beneficiary notice and appeal rights and can only occur prior to discharge and Part A billing, status changes are not an effective mechanism to

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24 In the Case of Sacred Heart Hospital, Medicare Appeals Council Decision at 8 (Nov. 10, 2009).
26 “A hospital outpatient is a person who has not been admitted by the hospital as an inpatient but is registered on the hospital records as an outpatient and receives services . . . from the hospital . . . .” BPM (CMS Pub. 100-02), ch. 6, § 20.2; CPM (CMS Pub. 100-04), ch. 1 § 50.3.1.
ensure that hospitals are reimbursed for the medically necessary services they provide when the length of stay is relatively short.

A. Utilization Review of Inpatient Admissions; Role of Treating Physician

1. Once a decision is made to admit a patient, his status remains as an inpatient until discharge or action is taken to change the patient’s status.

2. Utilization review requirements: Medicare Conditions of Participation (CoPs) require that a provider’s utilization review (UR) plan provide for review of the medical necessity of Medicare inpatient admissions, including the duration of inpatient stays. Reviews can be conducted before, at or after admission and may be conducted on a sample basis.

3. The determination that an admission or continued stay is not medically necessary can be made by one member of the UR committee if the physician responsible for the patient’s care while in the hospital (not necessarily the admitting physician) concurs or fails to express his views. Alternatively, two members of the UR committee may make the decision without the concurrence of the treating physician.

4. Beneficiaries are entitled to notice of a UR decision that an admission or continued stay is not medically necessary.

C. Inpatient to Outpatient Status Changes - Condition Code 44

1. To address situations where a UR committee determines that an inpatient admission is not medically necessary, CMS established the Condition Code 44 policy, which states:

   • Condition Code 44 -- Inpatient admission changed to outpatient -- For use on outpatient claims only, when the physician ordered inpatient services, but upon internal utilization review performed before the claim was originally submitted, the hospital determined that the services did not meet its inpatient criteria.

2. According to CMS’s manual, Condition Code 44 is “to address those relatively infrequent occasions, such as a late-night weekend admission when no case manager is on duty to offer guidance, when internal review subsequently determines that an inpatient admission does not meet

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27 42 C.F.R. § 482.30(c)(1).
28 Id. at § 482.30(c)(2)-(3).
29 Id. at § 482.30(d).
30 Id.
31 CPM (CMS Pub. 100-04), ch.1 § 50.3.1 (emphasis added).
hospital criteria and that the patient would have been registered as an outpatient under ordinary circumstances.”32

3. Requirements for Condition Code 44 billing:
   - change in status must be made prior to discharge
   - hospital has not submitted a claim for inpatient admission
   - treating physician and UR committee concur with change
   - concurrence is documented in patient record33

4. Medical record requirements for patient status change:
   - medical record must “fully document” status change, complete with order and notes indicating reason for change, care furnished and participants in making the decision
   - all orders and entries regarding the inpatient admission must be retained in the record in original form.34

5. Billing Rules If Requirements for Use of Condition Code 44 Are Met:
   - The entire episode of care should be billed as an outpatient episode of care on a 13x or 85x bill type and “outpatient services that were ordered and furnished should be billed as appropriate.”35
   - This would include “observation services” (see infra) but only for services provided after the point in time at which a physician specifically orders observation services. “Medicare does not permit retroactive orders or the inference of physician orders. Like all hospital outpatient services, observation services must be ordered by a physician.”36 In other words, even though a physician may have admitted the patient out of concern that his condition could lead to adverse consequences, CMS will not infer from the admission order that the physician would also have ordered observation services.

6. Billing Rules If Requirements for Use of Condition Code 44 Are Not Met:

32 Id.
33 Id. at § 50.3.2. According to CMS, the concurrence requirement is consistent with the Conditions of Participation which require consultation with the treating physician prior to a determination that inpatient admission is not necessary. CMS also states that it “may also be appropriate to include” the admitting physician in the review if different than that treating physician. Id.
34 Id.
35 Id.
36 Id.
Hospital may only submit a 12x bill type for covered “Part B Only Services.” Payable services include:

- diagnostic x-ray tests, lab tests and other diagnostic tests
- x-rays, radium, and radioactive isotope therapy
- surgical dressings, splints, casts and other devices for reduction of fractures
- prosthetic devices
- outpatient physical, occupational and speech language therapy
- a limited set of certain drugs, vaccines and limited screening services

No payment will be allowed for many other services that may have been provided, such as surgeries or drugs. No payment for observation services is allowed based on the view that only inpatient services were ordered, not observation services. Many hospitals find this policy unnecessarily restrictive considering that both inpatient services and observation services are generally ordered by a physician out of concern that a patient’s condition could result in adverse events.

Timely-filing deadlines for Part B claims also apply, which effectively preclude resubmission since RAC reopenings and denials often occur well after these deadlines.

7. In the FY 2013 Final OPPS rule, CMS stated that many hospitals indicated that admission decisions are often made late at night and on the weekends making it difficult to have adequate UR staffing available to timely review and change a beneficiary’s status prior to discharge as required by Condition Code 44.

III. Medicare Billing and Payment Rules Regarding Observation Services

In the most recent Outpatient Prospective Payment Final Rule (FY 2013), CMS noted that the number of cases of Medicare beneficiaries receiving observation services for more than 48 hours has increased from 3 percent in 2006 to approximately 7.6 percent in

37 Id.; BPM (CMS Pub. 100-02), ch. 6, § 10.
38 42 C.F.R. § 424.44.
The apparent increased use of observation services has implications for Medicare beneficiaries and has prompted litigation. This section sets forth CMS billing and payment requirements for observation services and discusses the claims in this litigation.

A. What are “observation services”?  
1. According to CMS, “[o]bservation 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.”

2. Observation services are only covered when ordered by a physician (or another individual authorized by state law). When ordered, the patient’s status is “outpatient.” “Observation” is not a patient status.

3. There is no specific time limit for observation services under Medicare rules, but according to CMS’s manual, “[i]n the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually less than 24 hours. In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours.”

B. Observation Billing Policy

1. As explained above, Medicare providers cannot “rebill” for observation services following the denial of an inpatient claim. According to CMS policy, observation services must be ordered by a physician prospectively for the purpose of determining whether an inpatient admission is necessary. Even though a physician may have ordered an inpatient admission based on his or her judgment that the patient’s condition might lead to adverse events, CMS will not interpret that admission as an order for observation services.

2. The start and end time for observation care must be recorded in the patient’s medical record. Observation time begins at the clock time documented in the patient’s record which should coincide with the time

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40 Id.
41 BPM (CMS Pub. 100-02), ch. 6, § 20.6; CPM (CMS Pub. 100-04), ch. 4, § 290.1.
42 Id.
43 Transmittal No. 1760, June 23, 2009 at 7-8 (“Editorial changes to the manuals remove references to ‘admission’ and ‘observation status’ in relation to outpatient observation services. . . .” * * * “These terms have been confusing to hospitals. . . . For payment purposes, there is no payment status called ‘observation’ . . . “).
44 CPM (CMS Pub. 100-04), ch. 1, § 50.3.2.
that observation care is initiated following a physician’s orders. Observation time ends when all clinical or medical interventions have been completed, including follow-up care that might take place after a physician has ordered the patient released or admitted as an inpatient.\textsuperscript{45} Observation time should be reported in hour-long units using HCPCS code G0378 (or G0379 for direct referral).

3. Standing orders for observation services following all outpatient surgeries are not recognized -- that is, payment will not be made in such cases.\textsuperscript{46}

4. Observation services cannot be billed concurrently with diagnostic or therapeutic services (such as a colonoscopy or chemotherapy) for which active monitoring is part of the procedure. Similarly, observation services do not include postoperative monitoring services that are part of the standard recovery period following a Part B service.\textsuperscript{47}

C. Payment for Observation Services

1. No separate payment is made for observation services.\textsuperscript{48} CMS considers payment for observation services to be packaged into payment for all other separately payable services that are rendered to the patient in the same encounter.\textsuperscript{49}

2. However, if a claim for observation services lasting 8 hours or longer is billed in combination with certain additional services (\textit{see} C.3., \textit{infra}), then the outpatient encounter will be classified into one of two APCs that will yield more payment than if observation services were not provided. To this end, Medicare recognizes two “extended care encounters” that include observation services of “substantial duration” (8 hours or more) -- Level I, Extended Assessment and Management Composite (APC 8002) and Level II, Extended Assessment and Management Composite (APC 8003).\textsuperscript{50}

\begin{itemize}
\item \textsuperscript{45} \textit{Id.} at § 290.2.2; § 290.5.1.
\item \textsuperscript{46} \textit{Id.}
\item \textsuperscript{47} \textit{Id.}
\item \textsuperscript{48} CPM (CMS Pub. 100-04), ch. 4, § 290.5.1; BPM (CMS Pub. 100-02), ch. 6, § 20.6.
\item \textsuperscript{49} BPM (CMS Pub. 100-02), ch. 6, § 20.6; CPM (CMS Pub. 100-04), ch. 4, § 290.1. Note: The billing and payment rules described in this section for observation services apply to services beginning on January 1, 2008. Prior rules permitted a separate APC payment under APC 0339 (Observation) for observation services furnished to patients with one of three qualifying diagnoses -- congestive heart failure, chest pain or asthma. CPM (CMS Pub. 100-04), ch. 4, § 290.4.3. Observation services are now packaged and paid through composite APCs. \textit{See} 72 Fed. Reg. 66580, 66810 \textit{et seq.} (Nov. 27, 2007).
\item \textsuperscript{50} CPM (CMS Pub. 100-04), ch. 4, § 290.5.1; BPM (CMS Pub. 100-02), ch. 6, § 20.6.
\end{itemize}
3. APC 8002 is used for patient encounters that include 8 or more hours of observation in conjunction with: a high-level clinic visit (Level 5) or a direct referral for observation.\textsuperscript{51}

4. APC 8003 is used for patient encounters that include 8 or more hours of observation in conjunction with: a high-level Type A or Type B emergency department visit or critical care services.\textsuperscript{52}

5. Observation services are subject to the 3-day DRG payment window; if a patient is later admitted, payment for the observation service is bundled with the inpatient admission and considered paid through the DRG payment.\textsuperscript{53}

IV. The Secretary’s Competing Policies on Payment for Services Following Inpatient Denials

According to CMS’s interpretation of the preceding rules, if an inpatient admission is denied, a hospital can bill for only a very limited set of Part B only services, not including observation services, because the hospital cannot meet the Condition Code 44 requirements. The Medicare Appeals Council, which is the final adjudicative decision-maker for the Secretary of Health and Human Services in Medicare claims appeals, points to other manual provisions and interprets them so as to allow payment for all medically necessary Part B services, including observation services. At least as of the date of the drafting of this outline, CMS has not acquiesced in these decisions, and providers are forced to file appeals after inpatient admission denials in order to be paid for the full range of these services.

A. Medicare Appeals Council Decisions

1. Hospitals have argued in Medicare claims appeals that they should be able to rebill and be paid by Medicare Part B for medically necessary services furnished during an inpatient admission when the admission is

\textsuperscript{51} CPM (CMS Pub. 100-04), ch. 4, § 290.5.1
\textsuperscript{52} \textit{id.}
\textsuperscript{53} CPM (CMS Pub. 100-04), ch. 3, § 40.3.
subsequently denied. This argument has been accepted by the Medicare Appeals Council on several occasions.\footnote{See, e.g., \textit{In the case of O’Connor Hospital}, Medicare Appeals Council (Feb. 1, 2010); \textit{In the case of UMDNJ - University Hospital}, Medicare Appeals Council (Mar. 14, 2005).}

2. In these decisions, the Medicare Appeals Council holds that CMS has stated in the Benefits Policy Manual, in Chapter 1, § 10 and Chapter 6, § 10, that Part B payment will be made for hospital services provided if Part A payment is denied.\footnote{See, e.g., \textit{In the case of Missouri Baptist Hospital}, Medicare Appeals Council at 9-10, relying upon BPM (CMS Pub. 100-02), ch. 6, § 10. The relevant language relied upon by the Appeals Council states, “Payment may be made under Part B for physician services and for the nonphysician medical and other health services listed below . . . to an inpatient,” if admission is disapproved as not reasonable and necessary. CMS relies upon this manual provision to limit payment to only a narrow list of items and services under the “Part B only” policy if Condition Code 44 is not followed. See \textit{supra}, Section II.} The Medicare Appeals Council also relies upon the Financial Management Manual (FFM), Chapter 3, § 170.1, which directs contractors to “ascertain whether the beneficiary is entitled to any Part B payment for the services in question,” when the contractor determines that a Part A overpayment has been made” and Chapter 29, § 280.3 of the Claims Processing Manual which recognizes that providers are entitled to correct payment for services that are not “covered as billed.”\footnote{Financial Management Manual (FMM) (CMS Pub. 100-06), ch. 3, § 170.1 (internally referring to the Part B payment policy in BPM (CMS Pub. 100-02), Chapter 6, § 10) and CPM (CMS Pub. 100-04), ch. 29, § 280.3 (“Claims Where There is Evidence That Items or Services Were Not Furnished or Were Not Furnished as Billed.”).} Timely filing limits do not apply to any rebillings, according to the Council, because the providers are making adjustments, or providing supplemental information about specific services provided to a specified individual, to correct claims that were submitted on a timely basis, a process allowed under CMS manuals.\footnote{See, e.g., \textit{In the case of Missouri Baptist Hospital} at 11, relying upon CPM (CMS Pub. 100-04), ch. 3, § 50.}

3. Remedy: The Medicare Appeals Council decisions generally order CMS’s contractors to review the services provided during the inpatient admission for coverage and payment under Part B. They typically do not, however, specify the exact manner in which to conduct this process, such as re-filling claims or making payment based on the denied claim as filed.\footnote{Id. at 12.}

4. Even though Medicare Appeals Council decisions are not binding on ALJs, ALJs now routinely remand cases for determinations of the amount that should be paid under Part B when they deny appeals for inpatient admissions.\footnote{CMS Memorandum, July 13, 2012 to All Fiscal Intermediaries, Carriers and Part A and Part B Medicare Administrative Contractors, (TDL -12309, 03-28-12) at 1.} CMS has instructed its contractors to pay when there are ALJ remands of this nature. These instructions, however, still cling to the Condition Code 44 policy in that they direct contractors not to pay for observation services unless the ALJ specified “observation level of care”
or “including observation care” in the order on the theory that “the ALJ is specifically substituting the order to admit for the order for observation.”


1. Plaintiffs include the American Hospital Association and several hospitals who have experienced RAC denials of inpatient admissions on the basis that, although the beneficiaries in question received medically necessary services, those services should have been treated on an outpatient basis. Plaintiffs further allege that they have not received Part B reimbursement for some or all of these medically necessary services due to CMS’s “Payment Denial Policy” -- identified in the complaint as the policy set forth in CMS’s Benefit Policy Manual, Chapter 6, § 10 -- i.e., the “Part B Only Services” policy (*see supra*, Section II.C.6).

2. Plaintiffs allege that CMS’s payment policy -- which only reimburses under Part B for a small list of ancillary services -- denies hospitals full payment for other services that must otherwise be covered under Part B, such as the costs of emergency room services, surgeries, drugs and observation services.

3. Plaintiffs’ complaint references the fact that the Medicare Appeals Council has ruled on a number of occasions that “Part B payment [is] available to hospitals that provide reasonable and medically necessary services on an inpatient basis when the patient could have been treated in the outpatient setting.”

4. Plaintiffs contend that CMS’s “Payment Denial Policy” violates the Medicare statute because it does not compensate plaintiffs for providing reasonable and medically necessary care; violates the Administrative Procedure Act because there is no non-arbitrary explanation or justification for the policy; violates the Administrative Procedure Act because CMS’s refusal to follow the Medicare Appeals Council’s precedent is arbitrary; and violates the Medicare statute and the Administrative Procedure Act because the policy was not promulgated through notice and comment rule-making.

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60 *Id.* at 2.
61 *American Hospital Association v. Sebelius*, 12-1770 (Nov. 1, 2012); Compl. at ¶ 53-77.
62 *Id.* at ¶ 44.
63 *Id.* at ¶ 6, 86.
64 *Id.* at ¶ 49.
65 *Id.* at ¶¶ 91-119.
V. Beneficiary Considerations

CMS has stated that its limited Part A to Part B rebilling policy following inpatient stay denials is, in part, driven by beneficiary rights. Specifically, a beneficiary’s status as an inpatient or outpatient may affect the amount of co-pays or deductibles for which the beneficiary is responsible. In addition, increased use of observation care by hospitals could increase a beneficiary’s financial responsibility for self-administered drugs and have an impact on his or her access to covered skilled nursing (SNF) benefits following discharge. Therefore, retroactive status changes to allow for full hospital billing following a denial for inpatient stay are disallowed.

A. Co-pays and Deductibles in Part A versus Part B

1. Medicare inpatients pay a one-time deductible for all hospital services provided during the first 60 days of a hospital stay. In comparison, outpatients must pay a co-pay for each individual service they receive. While the Medicare co-payment for a single outpatient service cannot be more than the inpatient hospital deductible, it is possible for a beneficiary to receive more than one outpatient service and the aggregate total of his co-payments to exceed the inpatient deductible.

2. Self-administered drugs provided in an outpatient setting are not covered by Part B. Therefore, hospitals may bill beneficiaries for self-administered drugs. In comparison, self-administered drugs would be bundled with the DRG payment if the beneficiary were admitted as an inpatient.

B. The Three-Day Inpatient Stay Requirement for SNF Coverage

1. Section 1861(i) of the Social Security Act requires that a beneficiary be an “inpatient” of a hospital for not less than 3 consecutive days before discharge from the hospital in order to be eligible for coverage of post-hospital extended care services under Part A. This requirement is repeated in CMS regulations which state that, among other requirements, a beneficiary must “[h]ave been hospitalized in a participating or qualified hospital or participating CAH, for medically necessary inpatient hospital
or inpatient CAH care, for at least 3 consecutive calendar days, not counting the date of discharge.66

2. Time spent in an emergency room or receiving observation services as an outpatient is not considered time spent hospitalized as an “inpatient” and, therefore, does not count toward the 3-day inpatient stay requirement.67 CMS has invited comments on this policy on recent occasions, but has never changed it.

3. According to CMS, a hospital’s decision to change the status of a patient from “inpatient” to “outpatient” after discharge would affect the beneficiary’s obligation for co-payments under Part B and could retroactively affect the beneficiary’s coverage of any SNF level of care.68

C. Bagnall v. Sebelius, 11-1703 (Nov. 3, 2011 D. Conn)

1. Plaintiffs in this proposed class action challenge CMS’s “use of observation status” and seek injunctive relief to halt its use.69

2. Among other things, beneficiaries allege:

   • “observation” care is, in many cases, indistinct from inpatient care and beneficiaries are often “observed” in the same wards of hospitals with inpatients;70
   • beneficiaries do not receive formal notice that they are being placed in “observation status” and there is no formal appeal mechanism to challenge this decision;71
   • after beneficiaries leave the hospital, they have no way to “appeal the Part B coverage of their hospitalization on the ground that coverage should have been under Part A;”72
   • CMS’s policy to prohibit rebilling under Part B when an inpatient admission is later denied incentivizes hospitals to place patients on “observation status.” RAC reviews of short-term admissions further this incentive.73
• Payment penalties for readmissions enacted with the Affordable Care Act incentivize hospitals to place beneficiaries in observation status;74

• the number of “observation claims” has increased dramatically since 2006, and the percentage of beneficiaries receiving observation services who remain longer than 48 hours has also increased significantly;75

• the use of “observation status” causes beneficiaries financial injury by increasing Part B co-pays, increasing self-administered drug costs paid for out-of-pocket and depriving beneficiaries of coverage of Part A SNF coverage.76

3. Among their legal claims, plaintiffs contend that the mere policy to allow “observation status” as a “billing mechanism” is arbitrary and capricious, has never been promulgated pursuant to notice and comment rule-making, and violates the Medicare statute because it denies beneficiaries Part A SNF coverage.77

4. Case status: the government has moved to dismiss plaintiffs’ lawsuit. The motion is pending.

VI. Recent CMS Developments

CMS has received significant pressure from stakeholders to address many of the issues raised by increased medical necessity denials of inpatient stays (many of which are reversed on appeal), CMS billing rules which prohibit rebilling under Part B for certain medically necessary services provided during patient encounters and the perceived increase in observation services. CMS’s response has been evolving, but its ultimate response will be measured by the extent to which it addresses the concerns of the various stakeholders involved, including hospital providers.

74 Id. ¶ 48.
75 Id. ¶¶ 50-51.
76 Id. ¶¶ 52-56.
77 Id. ¶¶ 94, 95 and 98.
A. Part A to Part B Rebilling Demonstration

1. Beginning January 1, 2012, CMS initiated the Medicare Part A to Part B Rebilling (AB Rebilling) Demonstration, which is slated to last 3 years.

2. Under the terms of the demonstration, participating hospitals that have Part A “short-stay” claims denied for lack of medical necessity may rebill the denied claims under Part B in order to receive Part B payment for services rendered during the encounter.

3. Rebilling is allowed outside the usual timely filing requirements. Hospitals may receive 90 percent of the Medicare allowable payment for all Part B services that would have been medically necessary had the beneficiary initially been treated as an outpatient.

4. While the list of Part B services for which a provider can rebill is presumably longer than the “Part B only” services that a hospital may bill for under CMS manuals (see supra), the hospital cannot rebill for observation services. Even under the terms of the demonstration, CMS will not waive its requirement that observation services must be prospectively ordered by a physician.

5. Participating hospitals must waive their right to appeal the inpatient stay denial, thereby giving up any chance of fully recovering the inpatient stay. Participating hospitals also may not bill beneficiaries for additional cost-sharing (co-pays and deductibles) or for self-administered drugs provided during the encounter.

6. The purported purpose of the AB Rebilling demonstration is to determine the effect of “expanded” rebilling on the Medicare Trust Funds, beneficiaries, hospitals and CERT error rate.

B. FY 2013 Proposed and Final Outpatient Prospective Payment (OPPS) Rule

1. In the FY 2013 OPPS proposed rule, CMS solicited comments on potential policy changes which could be made “to improve clarity and consensus among providers, Medicare, and other stakeholders regarding the relationship between admission decisions and appropriate Medicare payment, such as when a Medicare beneficiary is appropriately admitted to the hospital as an inpatient and the cost to hospitals associated with making this decision.”

2. In the proposed rule, CMS stated that the current rebilling policy following an inpatient denial (Condition Code 44) is designed to protect beneficiaries and provides disincentives to hospitals to admit patients inappropriately (suggesting that more liberal rebilling policies would

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78 77 Fed. Reg. at 68426.
encourage hospitals to err on the side of admission). CMS also acknowledged providers’ concerns that the Condition Code 44 policy does not adequately compensate providers for resources expended on services to beneficiaries in need of medically necessary care (albeit, according to CMS, not at the inpatient level of care). CMS further acknowledged hospitals’ concerns that they generally do not have the resources to conduct timely review of short-stay admissions, which account for a significant proportion of the CERT error rate, in order to follow the procedures necessary to change patient status prior to discharge.

3. CMS received over 350 comments in response to the proposed rule. In the FY 2013 Final OPPS Rule, CMS summarized, but did not respond to, comments, and categorized them into six subject matter areas:

- Part A to Part B Rebilling: These comments included support for the AB Rebilling Demonstration and many called for a national Part B rebilling rule, a policy allowing hospitals to change patient status after discharge and/or extension of the timely filing rules.

- Clarifying Current Admission Instructions or Establishing Specified Clinical Criteria: Whether admission criteria are sufficient clear, should be made clearer or should be based on evidence-based clinical standards (including the use of screening tools).

- Hospital Utilization Review

- Prior Authorization for Payment of Inpatient Admissions

- Time-Based Criteria for Inpatient Admissions

- Payment Alignment: Whether aligning payment rates more closely with the resources expended by a hospital when providing outpatient care versus inpatient care of short duration would influence admissions decisions.

C. Unified Agenda 2013

1. The most recent version of the Semiannual Regulatory Agenda (Unified Agenda) for Fall 2012 includes reference to a proposed rule entitled: Patient Status and Parts A and B Rebilling in Hospitals (CMS -1455-P):79

2. Abstract: “This proposed rule would address recent increases in the length of time that Medicare beneficiaries spend as outpatients receiving

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79 See Semiannual Regulatory Agenda Fall 2012 available at http://www.regulations.gov/#/documentDetail;D=HHS-ASAM-2012-0008-0001. The abstract is available under Regulation Identifier Number (RIN) 0938-AR73.
observation services. This rule also addresses hospital concerns about Medicare Part A to Part B rebilling policies when a hospital inpatient claim is denied because the inpatient admission was not medically necessary.”\textsuperscript{80}

3. NPRM expected date according to the abstract -- 01/00/2013

4. The abstract does not address whether the proposed rule will address revising inpatient admission standards, the use of screening tools by medical review contractors or the unification of contractor review standards to inpatient admission standards. Finally, the abstract does not foreshadow whether CMS will propose to eliminate its policy that a prospective order for “observation services” is required even in those cases in which a medical reviewer has denied the claim on the belief that the services actually provided were observation services.

\textsuperscript{80} \textit{Id.} In order to address these concerns in a meaningful way, it would seem necessary for the proposed rule to include a provision that would allow a physician’s inpatient order to be interpreted as an order for observation services.