

Year	Stationary sources (1)
2010	81,097,647
2011	78,787,371
2012	79,815,562

The SCAQMD's MOE reduction resulted from a loss of revenues due to circumstances beyond its control. EPA proposes to determine that the SCAQMD lower the FY2012 MOE level to \$108,291,832 to meet the CAA section 105(c)(2) criteria as resulting from a non-selective reduction of expenditures.

This notice constitutes a request for public comment and an opportunity for public hearing as required by the Clean Air Act. All written comments received by April 17, 2013 on this proposal will be considered. EPA will conduct a public hearing on this proposal only if a written request for such is received by EPA at the address above by April 17, 2013. If no written request for a hearing is received, EPA will proceed to the final determination. While notice of the final determination will not be published in the **Federal Register**, copies of the determination can be obtained by sending a written request to Gary Lance at the above address.

Dated: March 6, 2013.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2013-05923 Filed 3-15-13; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 414 and 419

[CMS-1455-P]

RIN 0938-AR73

Medicare Program; Part B Inpatient Billing in Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: The proposed rule would revise Medicare Part B billing policies when a Part A claim for an hospital inpatient admission is denied as not medically reasonable and necessary.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 17, 2013.

ADDRESSES: In commenting, please refer to file code CMS-1455-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this document to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1455-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1455-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Ann Marshall, (410) 786-3059, for issues related to payment of Part B inpatient and Part B outpatient services.

David Danek, (617) 565-2682, for issues related to hospital or beneficiary appeals.

Fred Grabau, (410) 786-0206, for issues related to time limits for filing claims.

Twi Jackson, (410) 786-1159, for information on all other issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Summary and Background

A. Executive Summary

1. Purpose

In the Calendar Year (CY) 2013 Hospital Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) proposed rule (July 30, 2012, 77 FR 45155 through 45157) and final rule with comment period (November 15, 2012, 77 FR 68426 through 68433), we expressed our ongoing concern about recent increases in the length of time that Medicare beneficiaries spend as hospital outpatients receiving observation services. (In this proposed rule, "hospital" means hospital as defined at section 1861(e) of the Social Security Act (the Act), but includes critical access hospitals (CAHs) unless otherwise specified. Although the term "hospital" does not generally include CAHs, section 1861(e) of the Act provides that the term "hospital"

includes CAHs if the context otherwise requires. In this case, we believe it is appropriate to propose to apply the same policies regarding payment for inpatient services under Part B in CAHs as apply in hospitals).

Observation services include short-term ongoing treatment and assessment for the purpose of determining whether a beneficiary can be discharged from the hospital or will require further treatment as an inpatient (Section 20.6, Chapter 6 of the Medicare Benefit Policy Manual (Pub. 100-02)). Beneficiaries who are treated for extended periods of time as outpatients receiving observation services may incur greater financial liability than if they were admitted as inpatients. They may incur financial liability for Medicare Part B copayments; the cost of self-administered drugs that are not covered under Part B; and the cost of post-hospital Skilled Nursing Facility (SNF) care, because section 1861(i) of the Act requires a prior 3-day hospital inpatient stay (toward which time spent receiving outpatient observation services does not count) for coverage of post-hospital SNF care under Medicare Part A. In the CY 2013 OPPTS/ASC proposed and final rules, we discussed how the trend towards the provision of extended observation services may be attributable in part to hospitals' concerns about Medicare Part A to Part B billing policies when a hospital inpatient claim is denied because the inpatient admission was deemed not medically necessary. Under longstanding Medicare policy, in these situations hospitals can only receive payment for a limited set of largely ancillary inpatient services under Part B.

In the CY 2013 OPPTS/ASC proposed rule (77 FR 45155 through 45157) and final rule with comment period (77 FR 68426 through 68433), we solicited and described the public comments received on potential clarifications or changes to our policies regarding patient status that may be appropriate to provide more clarity and consensus among providers, beneficiaries, and other stakeholders regarding the relationship between inpatient admission decisions and appropriate Medicare payment. We also provided an update on the Part A to Part B Rebidding (Part A/B) Demonstration that was slated to be in effect for CYs 2012 through 2014 and was designed to assist us in evaluating these issues. Having further considered the concerns raised in these comments as well as our experience with the Part A/B Demonstration, we are proposing to revise our Part B inpatient billing policy.

2. Summary of the Major Proposed Provisions

We propose that when a Medicare Part A claim for inpatient hospital services is denied because the inpatient admission was deemed not to be reasonable and necessary, or when a hospital determines under § 482.30(d) or § 485.641 after a beneficiary is discharged that his or her inpatient admission was not reasonable and necessary, the hospital may be paid for all the Part B services (except for services that specifically require an outpatient status) that would have been reasonable and necessary had the beneficiary been treated as a hospital outpatient rather than admitted as an inpatient, if the beneficiary is enrolled in Medicare Part B. We propose to continue applying the timely filing restriction to the billing of all Part B inpatient services, under which claims for Part B services must be filed within 1 year from the date of service. In this proposed rule, we also describe the beneficiary liability and other impacts of our proposals.

3. Summary of Costs and Benefits—Proposed Part B Inpatient Payment Policy

We estimate that the proposals in this proposed rule would result in an approximately \$4.8 billion decrease in Medicare program expenditures over 5 years. In section V. of this proposed rule we set forth a detailed analysis of the regulatory and federalism impacts that the proposed changes would have on affected entities and beneficiaries.

B. Legislative and Regulatory Authority/Prior Rulemaking

Under section 1832 of the Act, when Part A payment cannot be made for a hospital inpatient claim because the inpatient admission is determined not reasonable and necessary under section 1862(a)(1)(A) of the Act, we believe Medicare should pay all for Part B services (except for services that specifically require an outpatient status) that would have been reasonable and necessary if the hospital had treated the beneficiary as a hospital outpatient rather than treating the beneficiary as an inpatient. We have previously addressed this issue in prior rulemaking through the proposed and final rules titled Prospective Payment System for Hospital Outpatient Services, (September 8, 1998, 63 FR 47560; and April 7, 2000, 65 FR 18444; respectively); the proposed and final rule titled, Changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2002, (August 24,

2001, 66 FR 44698 through 44699) and (November 30, 2001, 66 FR 59891 through 59893 and 59915); and the final rule, titled Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; (November 29, 2010, 75 FR 73449 and 73627).

II. Proposed Payment of Medicare Part B Inpatient Services

A. Background

In the CY 2013 OPPTS/ASC proposed rule and final rule with comment period (77 FR 45155 through 45157 and 77 FR 68426 through 68433, respectively), we discussed that when a Medicare beneficiary arrives at a hospital in need of medical or surgical care, the physician or other qualified practitioner may admit the beneficiary for inpatient care or treat him or her as an outpatient. In some cases, when the physician or other qualified practitioner admits the beneficiary and the hospital provides inpatient care, a Medicare claims review contractor, such as a Medicare Administrative Contractor (MAC), a Recovery Audit Contractor (RAC), or a Comprehensive Error Rate Testing (CERT) Contractor, subsequently determines that the inpatient admission was not reasonable and necessary under section 1862(a)(1)(A) of the Act, and therefore denies the associated hospital Part A claim for payment. To date, under Medicare's longstanding policy, in these cases hospitals may bill a subsequent Part B inpatient claim for only a limited set of medical and other health services, referred to as "Part B inpatient" or "Part B only" services, even if additional services furnished would have been medically necessary had the beneficiary been treated as an outpatient. Under current Medicare policy, these Part B inpatient claims are considered new claims subject to the time limits for filing claims described at sections 1814(a)(1), 1835(a), and 1842(b)(3)(B) of the Act and 42 CFR 424.44 (see section II.G. of this proposed rule). We do not consider these claims to be adjustments to the originally submitted Part A claim.

Medicare's policy to pay only a limited set of medical and other health services as inpatient services under Part B when payment cannot be made under Part A has been in place for many years. As early as 1968, the Medicare manuals provided for payment under Part B of only a limited list of ancillary medical and other health services furnished to inpatients of participating hospitals (see Section 3110 of the Medicare Intermediary Manual and Section 2255C of the Medicare Carriers Manual,

replaced by Section 10, Chapter 6 of the Medicare Benefit Policy Manual (MBPM) (Pub. 100–02)), and under current policy, we continue to provide that the payable Part B inpatient services include only a limited set of ancillary services (66 FR 44698 through 44699; 66 FR 59891 through 59893, and 59915). Hospitals are required to submit a Part B inpatient claim (Type of Bill (TOB) 12x, or 85x for CAHs) within the usual timely filing requirements in order to be paid for these Part B inpatient services (75 FR 73449 and 73627).

We have provided in manual guidance that the limited set of Part B inpatient services could be paid if there was no Part A coverage for the following reasons:

- In prospective payment system (PPS) hospitals—

- ++ No Part A prospective payment is made at all for the hospital stay because of patient exhaustion of benefit days before admission;

- ++ The admission was disapproved as not reasonable and necessary (and waiver of liability payment was not made);

- ++ The day or days of the otherwise covered stay during which the services were provided were not reasonable and necessary (and no payment was made under waiver of liability);

- ++ The patient was not otherwise eligible for or entitled to coverage under Part A; or

- ++ For discharges before October 1997;

- No Part A day outlier payment is made for one or more outlier days due to patient exhaustion of benefit days after admission but before the case's arrival at outlier status, or because outlier days are otherwise not covered and waiver of liability payment is not made; or

- If only day outlier payment is denied under Part A, Part B payment may be made for only the services covered under Part B and furnished on the denied outlier days.

- In non-PPS hospitals, Part B payment may be made for services on any day for which Part A payment is denied (that is, benefit days are exhausted; services are not at the hospital level of care; or patient is not otherwise eligible or entitled to payment under Part A) (Section 10, Chapter 6 of the MBPM).

The services payable are as follows:

- Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests.

- X-ray, radium, and radioactive isotope therapy, including materials and services of technicians.

- Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations.

- Prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue), or all or part of the function of a permanently inoperative or malfunctioning internal body organ, including replacement or repairs of such devices.

- Leg, arm, back, and neck braces, trusses, and artificial legs, arms, and eyes including adjustments, repairs, and replacements required because of breakage, wear, loss, or a change in the patient's physical condition.

- Outpatient physical therapy, outpatient speech-language pathology services, and outpatient occupational therapy (see the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," § 220 and § 230).

- Screening mammography services.
- Screening pap smears.
- Influenza, pneumococcal pneumonia, and hepatitis B vaccines.

- Colorectal screening.
- Bone mass measurements.
- Diabetes self-management.
- Prostate screening.
- Ambulance services.
- Hemophilia clotting factors for hemophilia patients competent to use these factors without supervision).

- Immunosuppressive drugs.
- Oral anti-cancer drugs.
- Oral drug prescribed for use as an acute anti-emetic used as part of an anti-cancer chemotherapeutic regimen.
- Epoetin Alfa (EPO).

To enable beneficiaries to make informed financial and other decisions prior to hospital discharge, Medicare allows the hospital to change a beneficiary's inpatient status to outpatient (using condition code 44 on a Part B outpatient claim) and bill all reasonable and necessary services that it provided to Part B as outpatient services, but only if these conditions are met: (1) The change in patient status is made prior to discharge; (2) the hospital has not submitted a Medicare claim for the admission; (3) both the practitioner responsible for the care of the patient and the utilization review committee concur with the decision; and (4) the concurrence is documented in the medical record (See Section 50.3, Chapter 1 of the Medicare Claims Processing Manual (MCPM) (Pub. 100–04); MLN Matters article SE0622, Clarification of Medicare Payment Policy When Inpatient Admission Is

Determined Not To Be Medically Necessary, Including the Use of Condition Code 44: "Inpatient Admission Changed to Outpatient," September 2004). The hospital conditions of participation (CoPs) provide similar patient protections. For example, in accordance with 42 CFR 482.13(b), patients have the right to participate in the development and implementation of their plan of care and treatment, to make informed decisions, and to accept or refuse treatment. Informed discharge planning between the patient and the physician is important for patient autonomy and for achieving efficient outcomes.

Hospitals have expressed concern that the policy allowing only limited billing for Part B inpatient services provides inadequate payment for resources they expended to take care of beneficiaries in need of medically necessary hospital care, although not necessarily inpatient care. Also, hospitals have indicated that often they do not have the necessary staff (for example, utilization review staff or case managers) available after normal business hours to confirm physicians' decisions to admit beneficiaries. Thus, for short-stay admissions, the hospitals may be unable to complete a timely review and change beneficiaries' status from inpatient to outpatient prior to discharge in accordance with the condition code 44 requirements.

In the CY 2013 OPPTS/ASC proposed rule (77 FR 45156), we discussed that we have 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 determined not reasonable and necessary and denied upon contractor review by electing to treat beneficiaries as outpatients receiving observation services, often for longer periods of time, rather than admitting them as inpatients. In recent years, the number of cases of Medicare beneficiaries receiving observation services for more than 48 hours, while still small, has increased from approximately 3 percent in 2006 to approximately 8 percent in 2011. This trend is concerning because of its effect on Medicare beneficiaries. There could be significant financial implications for Medicare beneficiaries of being treated as outpatients rather than being admitted as inpatients, and we have published educational materials for beneficiaries to inform them of their respective liabilities.¹ As

¹ CMS Pamphlets: "Are You a Hospital Inpatient or Outpatient? If You Have Medicare—Ask!", CMS Product No. 11435, Revised, February 2011; "How

we discuss later in this proposed rule, the statute provides different cost sharing responsibilities for beneficiaries for Part A and Part B services. In addition, section 1861(i) of the Act requires a 3-day hospital inpatient stay (towards which any time spent receiving outpatient observation services prior to the calendar day of admission does not count) in order for a beneficiary to qualify for coverage of subsequent post-hospital care in a SNF. Therefore, treating beneficiaries as outpatients rather than inpatients or expanding the number of payable Part B inpatient services could impact the financial liability of some beneficiaries.

In light of concerns related to the impact of extended time as an outpatient on Medicare beneficiaries and the impact on hospitals of denials of hospital inpatient claims, we implemented a demonstration, the Part A to Part B (A/B) Rebilling Demonstration, for hospitals. The demonstration was initially slated to last for 3 years, from CYs 2012 through 2014. The demonstration allows a limited number of hospitals to rebill for additional Part B inpatient services outside the usual timely filing requirement, when Part A inpatient short-stay claims are denied because the inpatient admissions were determined not reasonable and necessary. Under the demonstration, hospitals may be eligible to receive 90 percent of payment for all Part B services that would have been reasonable and necessary had the beneficiaries been treated as outpatients rather than admitted as inpatients. We also solicited public comments in the CY 2013 OPPTS/ASC proposed rule on various policy clarifications or changes that have been suggested by stakeholders to address these issues, including revising our Part B inpatient billing policy (77 FR 45155 through 45157).

In an increasing number of cases, hospitals that have appealed Part A inpatient claims that were denied because the inpatient admission was not reasonable and necessary have received partially favorable decisions from the Medicare Appeals Council or Administrative Law Judges (ALJs). While upholding the Medicare review contractor's determination that the inpatient admission was not reasonable and necessary, the Medicare Appeals Council and ALJ decisions have ordered payment of the services as if they were rendered at an outpatient or "observation level" of care. These

decisions effectively require Medicare to issue payment for all Part B services that would have been payable had the beneficiary originally been treated as an outpatient (rather than an inpatient), instead of payment for only the limited set of Part B inpatient services that are designated in the MBPM. Moreover, these decisions have required such payment regardless of whether the subsequent hospital claim for payment under Part B is submitted within the otherwise applicable time limit for filing Part B claims. These Medicare Appeals Council and ALJ decisions providing for payment of all reasonable and necessary Part B services under the circumstances described previously are contrary to our longstanding policies that permit billing for only a limited list of Part B inpatient services and require that the services be billed within the usual timely filing restrictions (See Section 10, Chapter 6 of the MBPM (Pub. 100-02); 63 FR 47560; 65 FR 18444; 66 FR 44698 through 44699; 66 FR 59891 through 59893, and 59915; and 75 FR 73449, 73627). While decisions issued by the Medicare Appeals Council and ALJs do not establish Medicare payment policy, we are bound to effectuate each individual decision. The increasing number of these types of decisions has created numerous operational difficulties.

After reviewing the public comments we received in response to the CY 2013 OPPTS/ASC proposed rule, considering the most efficient way to effectuate the Medicare Appeals Council and ALJ decisions referenced earlier in this section, and further assessing our Part B inpatient payment policy, we are concurrently issuing this proposed rule and CMS Ruling 1455-R (hereinafter referred to as the Ruling). The Ruling establishes a standard process for effectuating these Medicare Appeals Council and ALJ decisions and handling claims and appeals while CMS considers how to best address this issue going forward. The Ruling also addresses the scope of administrative review in these and other, similar cases. Until this proposed rule is finalized, CMS, through the Ruling, acquiesces in the approach taken in the aforementioned Medicare Appeals Council and ALJ decisions on the issue of subsequent Part B billing following the denial of a Part A hospital inpatient claim on the basis that the inpatient admission was not reasonable and necessary. The Ruling is intended as an interim measure until we can finalize a policy to address the issues raised by these decisions going forward.

Specifically, the Ruling provides that when a Part A claim for a hospital inpatient admission is denied by a

Medicare review contractor because the inpatient admission was determined not reasonable and necessary, the hospital may submit a subsequent Part B inpatient claim for more services than just those listed in section 10, Chapter 6 of the MBPM, to the extent the services furnished were reasonable and necessary. The hospital may submit a Part B inpatient claim for payment for the Part B services that would have been payable to the hospital had the beneficiary originally been treated as an outpatient rather than admitted as an inpatient, except when those services specifically require an outpatient status. The Ruling only applies to denials of claims for inpatient admissions that were not reasonable and necessary; it does not apply to any other circumstances in which there is no payment under Part A, such as when a beneficiary exhausts Part A benefits for hospital services or is not entitled to Part A. Under the Ruling, Part B inpatient and Part B outpatient claims that are filed later than 1 calendar year after the date of service will not be rejected as untimely by Medicare's claims processing system as long as the corresponding denied Part A inpatient claim was filed timely in accordance with 42 CFR 424.44, consistent with the directives of the Medicare Appeals Council and ALJ decisions to which we are acquiescing.

The Ruling also provides that the A/B Rebilling Demonstration will be discontinued. We will communicate to hospitals and contractors the details regarding termination of the demonstration and implementation of Part B billing under the Ruling in future transmittals. As described in the Ruling, the Ruling is effective on its date of issuance. It applies to Part A hospital inpatient claims that were denied by a Medicare review contractor because the inpatient admission was determined not reasonable and necessary, as long as the denial was made: (1) While the Ruling is in effect; (2) prior to the effective date of the Ruling, but for which the timeframe to file an appeal has not expired; or (3) prior to the effective date of the Ruling, but for which an appeal is pending. The Ruling does not apply to Part A hospital inpatient claim denials for which the timeframe to appeal expired, and it does not apply to inpatient admissions determined by the hospital to be not reasonable and necessary (for example, through utilization review or other self-audit). The policy announced in the Ruling supersedes any other statements of policy on the issue of Part B inpatient billing following the denial by a

Medicare review contractor of a Part A inpatient hospital claim because the inpatient admission was not reasonable and necessary (although hospital outpatient services would have been reasonable and necessary), and it remains in effect until the effective date of the regulations that finalize this proposed rule. This proposed rule proposes revisions to our Part B payment policy that would apply prospectively from the effective date of the final regulations and would differ in some respects from the provisions of the Ruling, the purpose of which is to effectuate the Medicare Appeals Council and ALJ decisions.

B. Proposed Payable Part B Inpatient Services

Having reviewed the statutory and regulatory basis of our current Part B inpatient payment policy, we believe that, under section 1832 of the Act, Medicare should pay all Part B services that would have been reasonable and necessary (except for services that require an outpatient status) if the hospital had treated the beneficiary as a hospital outpatient rather than treating the beneficiary as an inpatient, when Part A payment cannot be made for a hospital inpatient claim because the inpatient admission is determined not reasonable and necessary under section 1862(a)(1)(A) of the Act. Therefore, in this section, we propose to revise our current policy to allow payment for additional Part B inpatient services than Medicare currently allows when CMS, a Medicare review contractor, or a hospital determines after discharge that payment cannot be made under Part A because a hospital inpatient admission was not reasonable and necessary, provided the statutorily required timeframe for submitting claims is not expired, as discussed in section II.G. of this proposed rule. The hospital could re-code the reasonable and necessary services that were furnished as Part B services, and bill them on a Part B inpatient claim. This proposed policy would only apply to denials of claims for inpatient admissions that are not reasonable and necessary, and would not apply to any other circumstances in which there is no payment under Part A, such as when a beneficiary exhausts Part A benefits for hospital services or is not entitled to Part A.

Specifically, we propose to revise our Part B inpatient billing policy to allow payment of all hospital services that were furnished and would have been reasonable and necessary if the beneficiary had been treated as an outpatient, rather than admitted to the hospital as an inpatient, except for those

services specifically requiring an outpatient status. We would exclude services that by statute, Medicare definition, or standard Healthcare Common Procedure Coding System (HCPCS) code are defined as outpatient services, including outpatient diabetes self-management training services (DSMT) defined in section 1861(qq) of the Act; outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services (PT/SLP/OT or “therapy” services) defined in section 1833(a)(8) of the Act; and outpatient visits, emergency department visits, and observation services (G0378, Hospital observation service, per hour; and G0379, Direct referral for hospital observation care). These services are, by definition, provided to hospital outpatients and not inpatients. Hospitals could only submit claims for Part B inpatient services that were furnished to an inpatient in accordance with their Medicare and standard Healthcare Common Procedure Coding System (HCPCS) code definitions, and in accordance with Medicare coverage and payment rules.

In accordance with section 1833(e) of the Act, hospitals would be required to furnish information as may be necessary in order to determine the amounts due for the services billed on a Part B inpatient claim for services rendered during the inpatient stay. We would implement this provision in proposed new 42 CFR 414.5, entitled, “Hospital inpatient services paid under Medicare Part B when a Part A hospital inpatient claim is denied because the inpatient admission was not reasonable and necessary, but hospital outpatient services would have been reasonable and necessary in treating the beneficiary.” The claim for inpatient Part B services would have to be submitted within the timely filing period (we discuss the time limits for filing claims in section II.G. of this proposed rule). To ensure the accuracy and appropriateness of payment under Part A, we propose that this policy would apply when CMS or a Medicare review contractor determines that the hospital inpatient admission was not reasonable and necessary, and also when a hospital determines under Medicare’s utilization review requirements in sections 1861(e)(6)(1) and 1861(k) of the Act and 42 CFR 482.30 (42 CFR 485.641 for CAHs) that a beneficiary should have received hospital outpatient rather than hospital inpatient services, but the beneficiary has already been discharged from the hospital (hereinafter referred to as

hospital “self-audit” for purposes of this preamble). In this circumstance, we would continue requiring the hospital to submit a “no pay/provider liable” Part A claim indicating that the provider is liable under section 1879 of the Act for the cost of the Part A services (see section 40.2.2(E), Chapter 3 of the MCPM). Submission of this Part A claim indicates that the provider is assuming financial liability for the denied items or services on the Part A claim consistent with section 1879 of the Act (and acknowledging that the beneficiary is not financially liable under section 1879 of the Act) for the cost of the Part A items and services. The claim also ensures accurate cost reporting, reporting of utilization of inpatient days, and triggers refund requirements of the Part A cost sharing under sections 1866(a) and 1879(b) of the Act and 42 CFR 411.402 of the regulations (see sections II.E. and F. of this proposed rule). Submitting the provider-liable Part A claim also cancels any claim that may have already been submitted by the hospital for payment under Part A. The hospital could then submit an inpatient claim for payment under Part B for all services that would have been reasonable and necessary if the beneficiary had been treated as a hospital outpatient rather than admitted as a hospital inpatient, except for those services specifically requiring an outpatient status. This claim would have to be submitted within the timely filing period (we discuss the time limits for filing claims in section II.G. of this proposed rule). We believe that providing for additional payment under Part B when a hospital determines itself that an inpatient admission was not reasonable and necessary but hospital outpatient services would have been reasonable and necessary would reduce improper payments under Part A, and would reduce the administrative costs of appeals for both hospitals and the Medicare program.

1. Part B Inpatient Services Paid Under the Hospital OPps

We propose payment of services that are paid under the OPps (except those requiring an outpatient status) under proposed new § 414.5(a)(1), “If a Medicare Part A claim for inpatient hospital services is denied because the inpatient admission was not reasonable and necessary, or if a hospital determines under § 482.30(d) or § 485.641 after a beneficiary is discharged that the beneficiary’s inpatient admission was not reasonable and necessary, the hospital may be paid for the following Part B inpatient services that would have been

reasonable and necessary if the beneficiary had been treated as a hospital outpatient rather than admitted as an inpatient, provided the beneficiary is enrolled in Medicare Part B: (1) Services described in § 419.21(a) that do not require an outpatient status.” We would exclude payment of services under the OPPS such as observation services and clinic visits that, by definition, require an outpatient status.

2. Services Excluded From Payment Under the OPPS

For the proposed Part B inpatient services furnished by the hospital that are not paid under the OPPS, but rather under some other Part B payment methodology, we propose that when the inpatient admission is determined not reasonable and necessary, Part B payment would be made pursuant to the respective Part B fee schedules or prospectively determined rates for which payment is made for these services when provided to hospital outpatients (see 65 FR 18442 and 18443). As provided in 42 CFR 419.22, the services for which payment is made under other payment methodologies are as follows:

- Ambulance services, as described in section 1861(v)(1)(U) of the Act, or, if applicable, the fee schedule established under section 1834(l) of the Act;
- Except as provided in 42 CFR 419.2(b)(11), prosthetic devices, prosthetics, prosthetic supplies, and orthotic devices;
- Except as provided in 42 CFR 419.2(b)(10), durable medical equipment supplied by the hospital for the patient to take home;
- Clinical diagnostic laboratory services;
- Effective December 8, 2003, screening mammography services and effective January 1, 2005, diagnostic mammography services (which would become paragraph (r) under our proposed redesignation, discussed in section II.C. of this proposed rule); and
- Effective January 1, 2011, annual wellness visit providing personalized prevention plan services as defined in 42 CFR 410.15 (which would become subparagraph (s) under our proposed redesignation, discussed in section II.C. of this proposed rule).

We propose to provide payment of these OPPS-excluded services in 42 CFR 414.5(a)(2) through (a)(7) as follows:

- Ambulance services, as described in section 1861(v)(1)(U) of the Act, or, if applicable, the fee schedule established under section 1834(l) of Act.
- Except as provided in § 419.2(b)(11), prosthetic devices,

prosthetics, prosthetic supplies, and orthotic devices.

- Except as provided in § 419.2(b)(10), durable medical equipment supplied by the hospital for the patient to take home.
- Clinical diagnostic laboratory services.
- Effective December 8, 2003, screening mammography services and effective January 1, 2005, diagnostic mammography services.
- Effective January 1, 2011, annual wellness visit providing personalized prevention plan services as defined in § 410.15 of this chapter.

In our review of the current regulations governing payment of Part B inpatient services, we noted an oversight in 42 CFR 419.22 that outpatient DSMT services which are described in section 1861(qq) of the Act and 42 CFR 414.63 and are paid under the Medicare Physician Fee Schedule (MPFS), were never excluded from OPPS payment along with all other physician services. Since the statute defines these services as outpatient services, § 414.63(e)(2) stipulates that outpatient DSMT services can be paid only if the beneficiary “[i]s not receiving services as an inpatient in a hospital, SNF, hospice, or nursing home.” Therefore, under our proposal these services would not be payable Part B inpatient services. However, pursuant to our review of the regulations, we propose a technical correction to clarify that outpatient DSMT services are excluded from OPPS payment. This correction would appear in § 419.22(u).

In addition, we noted a typographical error in paragraph (j), which should cross reference § 419.2(b)(11) rather than § 419.22(b)(11). We propose a technical correction to delete the erroneous “§ 419.22(b)(11)” and replace with “§ 419.2(b)(11)”. Also we noted that § 419.22(h) excludes “outpatient” therapy services from coverage under the OPPS. Section 1833(t)(1)(B)(iv) of the Act specifically states that “the term ‘covered OPD services’ * * (iv) does not include any therapy services described in subsection (a)(8)” and section 1833(a)(8) describes outpatient therapy services furnished by a hospital to a hospital outpatient or a hospital inpatient who is entitled to benefits under Part A but has either exhausted or is not so entitled to such benefits. In order to more clearly follow the statutory language defining covered OPD services, we propose to replace the words “outpatient therapy” with “therapy” in § 419.22(h) so that it reads, “Therapy services described in section 1833(a)(8) of the Act.”

We further noted that the headings of § 419.21 and § 419.22 describe the “hospital outpatient” services that are subject to (in § 419.21) or excluded from payment under (in § 419.22) the OPPS. To more appropriately describe the services that are payable under these regulations under the OPPS, we propose to amend the titles of these sections by removing the term “outpatient.” The title of § 419.21 would then read, “Hospital services subject to the outpatient prospective payment system.” The title of § 419.22 would then read, “Hospital services excluded from payment under the hospital outpatient prospective payment system.”

C. Billing for Part B Outpatient Services in the Three-Day Payment Window

The proposals in this proposed rule would not change the 3-day payment window policy, which requires payment for certain outpatient services provided to a beneficiary on the date of an inpatient admission or during the 3 calendar days (or 1 calendar day for a hospital that is not paid under the Inpatient Prospective Payment System (non-IPPS)) prior to the date of an inpatient admission to be bundled (that is, included) with the payment for the beneficiary’s inpatient admission, if those outpatient services are provided by the admitting hospital or an entity that is wholly owned or wholly operated by the admitting hospital (Section 40.3, Chapter 3 and Section 10.12, Chapter 4 of the Medicare Claims Processing Manual (Pub. 100.04)). The current policy applies to all diagnostic outpatient services and non-diagnostic (that is, therapeutic) services that are related to the inpatient stay. As stated in Section 10.12, Chapter 4 of the Medicare Claims Processing Manual, in the event that there is no Part A coverage for the inpatient stay, services provided to the beneficiary prior to the point of admission may be separately billed to Part B as the outpatient services that they were. This policy would continue to apply where Part A payment is not available. The Part B outpatient claims for the outpatient services provided in the 3-day (or 1-day for a non-IPPS hospital) payment window would be subject to the usual timely filing restrictions and not be considered adjustment claims (see section II.G. in this proposed rule).

Hospitals may only submit claims for Part B outpatient services that are reasonable and necessary in accordance with Medicare coverage and payment rules. In accordance with section 1833(e) of the Act, hospitals must furnish information as may be necessary

in order to determine the amounts due for the services billed on a Part B outpatient claim for services rendered in the 3-day payment window prior to the inpatient admission.

D. Applicability—Types of Hospitals

We propose that all hospitals billing Part A services be eligible to bill the proposed Part B inpatient services, including short-term acute care hospitals paid under the IPPS, hospitals paid under the OPPTS, long-term care hospitals (LTCHs), inpatient psychiatric facilities (IPFs), inpatient rehabilitation facilities (IRFs), CAHs, children's hospitals, cancer hospitals, and Maryland waiver hospitals. We propose that hospitals paid under the OPPTS would continue billing the OPPTS for Part B inpatient services. Hospitals that are excluded from payment under the OPPTS in 42 CFR 419.20(b) would be eligible to bill Part B inpatient services under their non-OPPTS Part B payment methodologies.

In the CY 2002 OPPTS proposed rule (66 FR 44698 through 44699) and final rule (66 FR 59891 through 59893), we recognized that certain hospitals do not submit claims for outpatient services under Medicare Part B, either because they do not have outpatient departments or because they have outpatient departments but submit no claims to Medicare Part B (for example, state psychiatric hospitals). When the OPPTS was implemented, the only claims these hospitals would ever have submitted for Part B payment would have been for the ancillary services designated as 'Part B Only' services. These hospitals were concerned about the administrative burden and prohibitive costs they would incur if they were to change their billing systems to accommodate OPPTS requirements solely to receive payment for Part B Only (Part B inpatient) services. Under our current policy of limited Part B inpatient billing following a reasonable and necessary Part A claim denial, the cost to these hospitals of implementing claims systems to bill Part B inpatient services to the OPPTS would have been greater than the payments they would have received for the services. In response to this concern, we revised 42 CFR 419.22 by adding paragraph (r), which provides that services defined in 42 CFR 419.21(b) that are furnished to inpatients of hospitals that do not submit claims for outpatient services under Medicare Part B are excluded from payment under the OPPTS. We provided an exception under which, rather than billing Part B inpatient services under the OPPTS, hospitals would bill these services under the

hospital's pre-OPPTS payment methodology, for example at reasonable cost or the per diem payment rate, unless the services were subject to a payment methodology that was established prior to the OPPTS. As described in section II.B. of this proposed rule, services subject to pre-OPPTS payment methodologies include PT/SLP/OT services; ambulance services; devices and supplies paid under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule; clinical diagnostic laboratory services; screening and diagnostic mammography services; and the annual wellness visit providing personalized plan prevention services.

We are soliciting public comments from these hospitals regarding the types of Part B inpatient services they anticipate billing Medicare under our proposal for payment of additional Part B services. If under our proposed policies, the Part B inpatient services payable to these hospitals would largely be limited to the ancillary services they currently bill Medicare, these hospitals would continue billing Part B inpatient services under the current exception. However, if we receive public comments indicating that hospitals subject to the exception in 42 CFR 419.22(r) would be eligible and seek payment for additional Part B inpatient services under this proposed rule, we would consider finalizing a policy to require these hospitals to bill the OPPTS since unlike under existing policy, their eligible payments would likely outweigh the cost of implementing billing systems specific to the OPPTS. To reflect such a policy, we would delete 42 CFR 419.22(r) and redesignate § 419.22(s) and § 419.22(t) as § 419.22(r) and § 419.22(s), respectively.

E. Beneficiary Liability Under Section 1879 of the Act

As discussed earlier in this proposed rule, our policy previously allowed for billing of only a limited set of Part B inpatient services rather than all Part B services following the reasonable and necessary denial of a Part A inpatient claim. We recognize the proposal would allow billing for additional Part B inpatient services, which could create a unique liability issue for Medicare beneficiaries that did not previously exist.

When a Part A inpatient admission is denied as not reasonable and necessary under section 1862(a)(1)(A) of the Act, or a hospital submits a "provider liable/no-pay" claim (following a self-audit as described in section II.B. of this proposed rule) indicating that the hospital has determined that an

inpatient admission is not reasonable and necessary, a determination of financial liability for the non-covered inpatient admission is made in accordance with section 1879 of the Act. The Medicare contractor determines whether the hospital and the beneficiary knew, or could have reasonably been expected to know, that the services were not covered. If neither the hospital nor the beneficiary knew, or could reasonably have been expected to know, that the services were not covered, then Medicare makes payment for the denied services. However, because hospitals are expected to have knowledge of our coverage and payment rules, hospitals are often determined liable under section 1879 of the Act for the cost of the non-covered items and services furnished. In addition, unless the beneficiary had knowledge of non-coverage in advance of the provision of services (typically through a Hospital Issued Notice of Non-Coverage (HINN)), the beneficiary will not be financially liable for the denied Part A services in accordance with section 1879 of the Act.

Following a denial of a Part A inpatient admission as not reasonable and necessary and a determination that the beneficiary was not financially liable in accordance with section 1879 of the Act, the hospital is required to refund any amounts paid by the beneficiary (such as deductible and copayment amounts) for the services billed under Part A. (See, 42 CFR 411.402.) The beneficiary would have no out-of-pocket cost in this scenario. However, under the Part B inpatient billing policy proposed in this rule, if the hospital subsequently submits a timely Part B claim after the Part A claim is denied, the financial protections afforded under section 1879 of the Act to limit liability for the denied Part A claim cannot also be applied to limit liability for the covered services filed on the Part B claim. The beneficiary (who may previously have had no out-of-pocket costs for the denied Part A claim) is responsible for applicable deductible and copayment amounts for Medicare covered services, and for the cost of items or services never covered (or always excluded from coverage) under Part B of the program. (The beneficiary's responsibility for payment of deductible, cost-sharing, and items excluded from coverage under Part B is discussed further in section II.F. of this proposed rule.) If, however, a hospital does not bill under Part B in a timely manner, in accordance with section 1866(a)(1)(A)(i) of the Act, the hospital may not charge the beneficiary for any costs related to

the Part B items and services furnished, if the beneficiary would otherwise be entitled to have Part B payment made on his/her behalf. Finally, in instances where the beneficiary is not enrolled in Medicare Part B, we encourage hospitals and beneficiaries to recognize the importance of billing supplemental insurers and pursuing an appeal of the Part A inpatient claim denial, as appropriate.

We do not believe that the existing beneficiary liability notices used in the Medicare fee-for-service program (the HINN and Advance Beneficiary Notice of Noncoverage (ABN)) are applicable or relevant for the Part B inpatient billing process described in this proposed rule to alert beneficiaries to the possible change in deductible and cost-sharing if a Part A inpatient claim is denied and a Part B claim is subsequently submitted. These notices must be given prior to the provision of an item or service that is expected to be denied, and cannot be issued retroactively (that is, after the receipt of the post-payment Part A inpatient claim denial). We would conduct an educational campaign and issue materials that address various aspects of this rulemaking, including raising beneficiary awareness that certain denied Part A inpatient hospital services may be covered under Part B of the program. We welcome public comment on recommendations for notification to beneficiaries in these situations, consistent with our current notice policies. (For additional information on beneficiary notices, see the CMS Web site at <http://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html>).

F. Applicable Beneficiary Liability: Hospital Services

As we note in section II.E. and section V. of this proposed rule, increasing the number of billable Part B inpatient services could affect beneficiary liability. In accordance with statute, beneficiary cost-sharing under Part A is different (and, in some cases, may be less) than under Part B. The CY 2013 Part A inpatient deductible and coinsurance amounts, which are set in accordance with statute, were recently announced in a notice published in the November 21, 2012 **Federal Register** (77 FR 69848 through 69850). Under Part A, a beneficiary pays a one-time deductible for all hospital inpatient services provided during the first 60 days in the hospital of the benefit period; therefore, an inpatient deductible does not necessarily apply to all hospitalizations. Part A coinsurance only applies after the 60th day in the hospital. A

beneficiary would be entitled to refunds of any amounts he or she paid to the hospital for the Part A claim if the hospital, but not the beneficiary, is held financially responsible for denied services under section 1879 of the Act (42 CFR 411.402.) However, under our proposed policy, beneficiaries would continue to be liable for their usual Part B financial liability.

Beneficiaries would be liable for Part B copayments for each hospital Part B outpatient or Part B inpatient service and for the full cost of drugs that are usually self-administered, which section 1861(s)(2)(B) of the Act does not include. We note that self-administered drugs are typically covered under Medicare Part D, and beneficiaries who have Part D coverage may submit a claim to their Part D plan for reimbursement of these costs. If a beneficiary must receive the self-administered drug from a hospital, rather than a community pharmacy, he or she would likely be subject to higher out-of-pocket costs due to the hospital pharmacy's status as a non-network pharmacy. Hospital billing systems, Part D reimbursement rates, and drug utilization review requirements make it difficult for hospitals to participate as a Part D network provider for these drugs. Therefore, if coverage is available, consistent with 42 CFR 423.124(b), beneficiaries would be responsible for the difference between the Part D plan's plan allowance and the hospitals' charges, and the difference may be significant. Thus under our proposed Part B billing policy, some beneficiaries who are entitled to coverage under both Part A and Part B may have a greater financial liability for hospital services compared to current policy, as they would be liable for additional Part B services billed when the inpatient admission is determined not reasonable and necessary. We are soliciting comment on whether we should consider additional policies to mitigate or prevent this potential additional liability for beneficiaries.

Most supplemental insurers or benefit programs (this includes but is not limited to Medigap plans that market Medicare supplemental insurance policies, employer retiree plans, FEHBP, TRICARE, and Medicaid) participate in Medicare's coordination of benefits (COB) or claims crossover process. Such payers sign national agreements with Medicare to facilitate the automatic transfer of Medicare-adjudicated professional as well as facility claims to them. Most, if not all of these supplemental insurers elect to receive Medicare crossover claims if there is cost-sharing (that is, deductible or co-

insurance amounts remains for the beneficiary to pay). The vast majority of insurers that pay after Medicare currently accept Part B physician claims as well as outpatient-oriented hospital claims as part of the Medicare crossover process. Therefore, if we finalize our proposal to allow for hospital billing of additional Part B services using claims whose National Uniform Billing Committee (NUBC) approved type of bill (TOB) designation is 12x (Hospital-Inpatient Part B), the vast majority of providers will find that their patients' claims will be automatically transferred to their supplemental insurance programs for further payment consideration. Additionally, to ensure that supplemental payers would coordinate benefits with Medicare successfully and pay benefits appropriately, Medicare would communicate with all supplemental payers to ensure they know: (1) What additional services beyond those traditionally termed "ancillary" would now be included under the TOB 12x designation; and (2) what new cost sharing this change in billing and payment methodology will impose. The Medicare crossover process currently in place will ensure that, for the most part, providers are not inconvenienced by having to bill their patients' supplemental insurance plans or programs for balances owed following Medicare's payment.

G. Time Limits for Filing Claims

Sections 1814(a)(1), 1835(a), and 1842(b)(3)(B) of the Act establish time limits for filing Medicare Part A and B claims. Section 424.44 of the regulations implements those sections of the Act and requires that all claims for services furnished on or after January 1, 2010 be filed within 1 calendar year after the date of service unless an exception applies. In the November 29, 2010 final rule with comment period (75 FR 73627) titled, "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011" modifying § 424.44, commenters requested that we create an exception to the time limits for filing claims so that hospitals are permitted to file inpatient Part B only claims for any inpatient cases that are retrospectively reviewed by a Medicare Recovery Audit Contractor (RAC) or other review entity and determined not to be medically necessary in an inpatient setting. Commenters requested that an exception be created at § 424.44(b) to allow for the billing of Part B inpatient and Part B outpatient claims when there is no coverage under Part A for a hospital stay. For the reasons discussed

in the November 29, 2010 final rule, we declined to create such an exception and we continue to believe that was the correct decision.

Under CMS Ruling 1455–R (published concurrently elsewhere in this issue of the **Federal Register**), we adopted (although we did not endorse) the views of the Medicare Appeals Council and many ALJs that subsequent Part B rebilling is allowed after the timely filing period has expired. The Ruling states that subsequent Part B inpatient and Part B outpatient claims that are filed later than 1 calendar year after the date of service are not to be rejected as untimely by Medicare's claims processing system as long as the original corresponding Part A inpatient claim was filed timely pursuant to 42 CFR 424.44. The Ruling remains in effect until the effective date of final regulations that result from this proposed rule. At that time, the final rule would supersede the Ruling's treatment of claims that providers file later than 1-calendar year after the date of service.

Accordingly, we propose a new § 414.5(b) that would require that claims for billed Part B inpatient services be rejected as untimely when those Part B claims are filed later than 1 calendar year after the date of service. Our proposal treats these Part B claims as new claims subject to the timely filing requirements, instead of as adjustment claims. This is consistent with longstanding Medicare policy because an adjustment claim supplements information on a claim that was previously submitted without changing the fundamental nature of that original claim. In these Part B claim situations, however, the fundamental nature of the originally filed claim is changed completely (from a Part A claim to a Part B claim).

Therefore, in order to remove any ambiguity, if this rule is finalized as proposed, billed Part B inpatient claims would be rejected as untimely when those Part B claims are filed later than 1-calendar year after the date of service. Moreover, because it is the responsibility of providers to correctly submit claims to Medicare by coding services appropriately, it is important to note that the exception located at § 424.44(b)(1), which extends the time for filing a claim if failure to meet the deadline was caused by error or misrepresentation of an employee, contractor or agent of HHS (commonly referred to as the "administrative error" exception), would not apply in situations where a provider bills the originally submitted Part A claim incorrectly. Finally, we remind

providers that in accordance with 42 CFR 405.926(n), determinations that a provider failed to submit a claim timely are not appealable.

H. Appeals Procedures

If a hospital is dissatisfied with an initial or revised determination by a Medicare contractor to deny a Part A claim for an inpatient admission as not reasonable and necessary, the hospital may either submit Part B inpatient or outpatient claims (consistent with this proposed rule) or file a request for appeal of the denied Part A claim in accordance with the procedures in 42 CFR Part 405 subpart I. In order to prevent duplicate billing and payment, a hospital may not have simultaneous requests for payment for the same services provided to a single beneficiary on the same dates of service. (See IOM Pub. 100–4, Chapter 1, section 120.) This includes requests for payment under both Part A and Part B. Thus, if a hospital chooses to submit a Part B claim for payment following the denial of an inpatient admission on a Part A claim, then the hospital cannot also maintain its request for payment for the same services on the Part A claim (including an appeal of the Part A claim). In this situation, before the hospital submits a Part B claim, it must ensure that there is no pending appeal request on the Part A claim. (A pending appeal means an appeal for which there is no final or binding decision or dismissal.) If the hospital has filed a Part A appeal, the appeal must be withdrawn, or the decision must be final or binding, before the Part B claim can be processed. If a hospital submits a Part B claim for payment without withdrawing its appeal request, the Part B claim would be denied as a duplicate. In addition, once a Part B claim is filed, there would be no further appeal rights available with respect to the Part A claim. However, the hospital and beneficiary would have appeal rights with respect to an initial determination made on the Part B claim under existing policies set forth at 42 CFR part 405 subpart I.

Additionally, if a beneficiary files an appeal of a Part A inpatient admission denial, a hospital cannot utilize the Part B billing process proposed in this rule to extinguish a beneficiary's appeal rights. Therefore, the hospital's submission of a Part B claim would not affect a beneficiary's pending appeal or right to appeal the Part A claim. If a beneficiary has a pending Part A appeal for an inpatient admission denial, then any claims rebilled under Part B by the hospital would be denied as duplicates by the Medicare contractor. As

explained previously, in order for the Part B claim(s) to be processed, the Part A appeal must be final or binding or dismissed. For example, if a beneficiary receives an unfavorable reconsideration on a Part A inpatient claim and does not file a timely request for hearing before an ALJ, the reconsideration decision becomes binding. At that point, the hospital could submit a Part B claim, provided it is filed within 12 months from the date of service. (See proposed 42 CFR 414.5(b) and 42 CFR 424.44).

As discussed in sections II.E and F. of this proposed rule, beneficiaries who are not enrolled in Medicare Part B may be liable for the cost of items and services associated with a hospital stay when billed under the Part B billing process proposed in this rule. We believe that some beneficiaries who are not enrolled in Medicare Part B may have other health insurance that might pay for some or all of the Part B items and services. If a beneficiary is not enrolled in Part B of the program, we strongly encourage the hospital to submit a Part B claim to Medicare before billing the beneficiary so that, when appropriate, the beneficiary's supplemental insurer receives the claim.

We are also clarifying in this proposed rule the scope of review with respect to appeals of Part A inpatient admission denials in the context of the Part B billing policy. As explained in CMS Ruling 1455–R, a large number of recent appeal decisions for Part A inpatient admission claim denials by Medicare review contractors have affirmed the Part A inpatient admission denial, but ordered that payment be issued as if services were provided at the outpatient or "observation" level of care under Part B of the Medicare program. These decisions ordered payment under Part B (or consideration of payment for services furnished that the contractor determined to be covered and payable under Part B) even though a Part B claim had not been submitted for payment. Hospitals are solely responsible for submitting claims for items and services provided to beneficiaries and determining whether submission of a Part A or Part B claim is appropriate. Once a hospital submits a claim, the Medicare contractor can make an initial determination and determine any payable amount (42 CFR 405.904(a)(2)). Under existing Medicare policy, if such a determination is appealed, an appeals adjudicator's scope of review is limited to the claim(s) that are before them on appeal, and such adjudicators may not order payment for items or services that have not yet been billed or have not yet received an initial determination. (See 42 CFR 405.920,

405.940, 405.948, 405.954, 405.960, 405.968, 405.974, 405.1000, 405.1032, 405.1100, and 405.1128.) For example, if a hospital submits an appeal of a determination that a Part A inpatient admission was not reasonable and necessary, the only issue before the adjudicator is the propriety of the Part A claim, not an issue involving any potential Part B claim the hospital has not yet filed. In making a decision on that Part A claim, an appeals adjudicator may not develop information, or make a finding, with respect to a Part B claim that does not exist.

Thus, under the billing processes described in this proposed rule, if a hospital appeals a Part A inpatient admission denial and receives a decision indicating that payment may not be made under Part A, appeals adjudicators may not order payment for items and services not yet billed under Part B. Rather, payment for items and services that may be covered under Part B may only be made in response to a Part B claim submitted by the hospital that is timely filed under proposed 42 CFR 414.5(b) and 42 CFR 424.44.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

With regard to the proposed payment of Medicare Part B inpatient services as discussed in section II.B. of this proposed rule, the medical recordkeeping requirement associated with the services billed on Part B inpatient claims during the inpatient

stay is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). The same holds for recordkeeping associated with the services billed on a Part B outpatient claim for services rendered in the 3-day payment window prior to the inpatient admission. We believe that the time, effort, and financial resources necessary to comply with the aforementioned recordkeeping requirements would be incurred by persons in the normal course of their activities; and therefore, considered to be usual and customary business practices.

With regard to the appeals of proposed payment of Medicare Part B inpatient services, the appeals information collection activity discussed in section II.H. of this proposed rule is exempt from the requirements of the Paperwork Reduction Act since it is associated with an administrative action (5 CFR 1320.4(a)(2) and (c)).

The aforementioned provisions would not impose any new or revised reporting or recordkeeping requirements and would not impose any new or revised burden estimates.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS-1455-P], Fax: (202) 395-6974; or Email: OIRA_submission@omb.eop.gov.

IV. Response to Comment

Because of the large number of public comments we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is needed to address Medicare Part A to Part B billing policies when a hospital inpatient claim is denied because the inpatient admission was not reasonable and necessary.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Contract with America Advancement Act of 1996 (Pub. L. 104-121) (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated as an “economically” significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Contract with America Advancement Act of 1996 (Pub. L. 104 121). Accordingly, the proposed rule has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this proposed rule. In this proposed rule, we are soliciting public comments on the regulatory impact analysis provided. The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration’s size standards with total revenues of \$34.5 million or less in any single year. We estimate that this proposed rule may have a significant impact on approximately 2,053 hospitals with voluntary ownership. For details, see the Small Business Administration’s “Table of Small Business Size Standards” at <http://www.sba.gov/content/table-small-business-size-standards>.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule may have a significant impact on approximately 708 small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold level is currently approximately \$141 million. This proposed rule does mandate requirements for the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and a subsequent final rule) that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has federalism implications. We have examined the provisions included in this proposed rule in accordance with Executive Order 13132, federalism, and have determined that they will not have a substantial direct effect on state, local or tribal governments, preempt state law, or otherwise have a federalism implication. As reflected in Table 1 of this proposed rule, we estimate that Medicare expenditures will increase for services furnished in governmental hospitals (including state and local governmental hospitals). The analyses we have provided in this section of the proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

C. Estimated Impacts of the Proposed Part B Inpatient Payment Policy

1. Estimated Impact on Medicare Program Expenditures

In this section, we provide the estimated impact of our proposal to provide payment for additional Part B inpatient services on Medicare benefit expenditures over the next 5 years. Column (3) of Table 1 shows the estimated impacts of this proposal, relative to an estimated increase in

baseline expenditures that will result from the effectuation of recent decisions by the Medicare Appeals Council and ALJs on Medicare Part A to Part B “rebilling” (in this section referred to as the “appeal decisions”).

In section II.A. of this proposed rule, we discuss that in an increasing number of cases, hospitals that have appealed Part A inpatient claim denials to the ALJs and the Medicare Appeals Council have received decisions upholding the Medicare review contractor’s determination that the inpatient admission was not reasonable and necessary, but ordering payment of the services as if they were rendered at an outpatient or “observation level” of care. These decisions effectively require Medicare to issue payment for all Part B services that would have been payable had the beneficiary originally been treated as an outpatient instead of limiting payment to only the set of Part B inpatient services designated in the Medicare Benefit Policy Manual. Further, the decisions have required payment regardless of whether the subsequent hospital bill for payment under Part B is submitted within the otherwise applicable time limit for filing Part B claims. The ALJ and Medicare Appeals Council decisions providing for payment of all reasonable and necessary Part B services under these circumstances are contrary to CMS’ longstanding policies that permit billing for only a limited list of Part B inpatient services and require that the services be billed within the usual timely filing restrictions. While these appeal decisions do not establish Medicare payment policy, CMS’ contractors are bound to effectuate each individual decision. Column (1) shows the estimated impacts of CMS’ instructions to contractors for effectuating the decisions that have been issued. To resolve the discrepancy between current Medicare policy and the decisions being made by the Medicare Appeals Council and ALJs, we are issuing CMS Ruling 1455–R concurrent with this proposed rule. As we describe in section II.A. of this proposed rule, the Ruling provides a standard process for effectuation of these appeal decisions through payment of additional Part B inpatient (rather than Part B outpatient or “observation”) services than current policy allows, in order to address the approach taken by ALJs and the Medicare Appeals Council for Part A hospital claims denied because an inpatient admission was not reasonable and necessary, but ordering payment of services as if they were rendered at an outpatient or “observation level” of care. Under the

Ruling, we will not apply the timely filing limitations in 42 CFR 424.44 to the subsequent claims for Part B services, but rather will afford the hospital 180 days from the date of receipt of a final or binding appeal decision, or 180 days from the date of receipt of the Part A initial determination or revised determination if there is no pending appeal, to file its Part B claim(s). Under the Ruling, hospitals are not required to appeal a claim denial prior to billing Part B; therefore, there is an added cost for the Ruling (shown in Column (2)) in addition to the cost of effectuating the appeal decisions (Column (1)).

The Ruling is in effect until this proposed rule titled, “Medicare Program; Part B Inpatient Billing in Hospitals”—is finalized, which will supersede the Ruling. The Ruling permits Part B inpatient billing as described previously for Part A hospital inpatient claims that were denied by a Medicare review contractor because the inpatient admission was determined not reasonable and necessary, as long as the denial was made: (1) While the Ruling is in effect; (2) prior to the effective date of the Ruling, but for which the timeframe to file an appeal has not expired; or (3) prior to the effective date of the Ruling, but for which an appeal is pending. In this proposed rule, we propose revisions to our Part B inpatient payment policy which would apply prospectively from the effective date of the finalized regulation for this proposed rule, and would differ in some respects from provisions of the Ruling, the purpose of which is to effectuate the appeal decisions. The key differences between the Ruling and the proposed policy are: (1) The proposed policy would apply the current timely filing restriction to the subsequent Part B inpatient claims rebilled after the Part A claim denial (that is, covered the Part B inpatient claims would only be paid if they are billed within 12 months of the date of service, which, as described previously, is not the case for the subsequent Part B inpatient claims rebilled under the Ruling); and (2) the proposed policy would apply when hospitals determine through self-audit that an inpatient admission is not reasonable and necessary (also subject to the timely filing limits).

The estimates for each column of Table 1 assume that the policy in the preceding column is already in place. Specifically, the estimated cost for the Ruling is relative to a baseline that includes the effect of the appeal decisions. Similarly, the estimated costs under this proposed rule are in relation to a baseline that includes both the

appeal decisions and the Ruling in place. We assumed short-stay inpatient utilization would increase by 1 percent as a result of the appeal decisions because hospitals would be able to rebill after an appeal. (There are currently no controls in place to monitor hospitals for changes in their inpatient growth trend and/or error rate.) In addition, we assumed short-stay inpatient utilization would increase by an additional 3 percent under the Ruling, since

hospitals could rebill under Part B without the expense of an appeal. Due to the timely filing restrictions and lower Part B payment rate for rebilling, we assumed there would be no increase in any inpatient utilization resulting from the proposed regulatory change to restrict inpatient Part B billing to the timely filing requirement of 12 months from the date of service, relative to circumstances prior to the appeal decisions. The 12-month timely filing

restriction imposed by the proposed regulation would greatly limit the capacity in which a hospital could rebill and thereby substantially reduces the number of Part B inpatient claims rebilled by hospitals, largely offsetting the higher costs arising from the appeal decisions and the Ruling. The amounts are shown in millions for CYs 2013 through 2017.

TABLE 1—ESTIMATED IMPACT ON MEDICARE PROGRAM EXPENDITURES FOR HOSPITAL SERVICES
(Current year dollars (in millions))

Calendar year	Appeal decisions	CMS ruling 1455-R	Part B inpatient billing with 12-month timely filing restriction proposed policy	Total impact
	(1)	(2)	(3)	(4)
2013	\$290	\$560	\$0	\$850
2014	410	770	– 1,140	40
2015	410	780	– 1,160	40
2016	430	830	– 1,210	50
2017	460	870	– 1,280	50

We note the following caveats relating to these cost estimates. First, the estimated financial effects are very sensitive to certain specifications of the proposed policy. For example, if the 12-month timely filing restriction on rebilling were to apply from the “date of denial”, rather than from the “date of service”, then the savings under the proposed policy would be much smaller than shown here. Second, the actual costs or savings would depend

substantially on possible changes in behavior by hospitals, and such behavioral changes cannot be anticipated with certainty. The estimates are especially sensitive to the assumed utilization changes in inpatient and outpatient utilization. While we believe that these assumptions are reasonable, relatively small changes would have a disproportionate effect on the estimated net costs.

2. Estimated Impact on Beneficiaries

Table 2 contains the aggregate impacts on beneficiary out-of-pocket expenses for Parts A and B, as a result of the appeal decisions, the Ruling, and this proposed rule. These changes are mainly the result of the changes in beneficiary cost-sharing when inpatient services are paid under Part B rather than under Part A. The amounts are shown in millions for CYs 2013 through 2017.

TABLE 2—ESTIMATED IMPACT ON BENEFICIARIES’ OUT-OF-POCKET EXPENSES FOR PART A AND PART B SERVICES
(Current year dollars (in millions))

Calendar year	Part A	Part B	Total
Appeal Decisions			
2013	\$20	\$20	\$40
2014	30	30	60
2015	30	30	60
2016	30	30	60
2017	30	30	60
CMS Ruling #1455-R			
2013	50	– 40	10
2014	80	– 60	20
2015	80	– 60	20
2016	80	– 60	20
2017	90	– 70	20
Proposed Part B Inpatient Billing With 12-Month Timely Filing Restriction Policy			
2013	0	0	0
2014	– 100	40	– 60
2015	– 100	40	– 60
2016	– 110	50	– 60

TABLE 2—ESTIMATED IMPACT ON BENEFICIARIES' OUT-OF-POCKET EXPENSES FOR PART A AND PART B SERVICES—
Continued
[Current year dollars (in millions)]

Calendar year	Part A	Part B	Total
2017	– 110	50	– 60
Total			
2013	70	– 20	50
2014	0	20	20
2015	0	20	20
2016	0	20	20
2017	0	20	20

Note: Totals do not necessarily equal the sums of rounded components.

3. Effects on Other Providers

This proposed rule would not affect providers other than hospitals.

4. Effects on the Medicaid Program

This proposed rule will not affect expenditures under the Medicaid program.

D. Effects of Other Policy Changes

We are not proposing to make other changes in this proposed rule.

1. Anticipated Effects on the Medicare Program—Part B Claims and Appeals

Under this proposed rule, hospitals would be able to file Part B inpatient claims when payment cannot be made for an inpatient admission under Part A. As discussed in section II.G of this proposed rule, hospitals must submit the Part B inpatient claim to the appropriate contractor within the timely filing limits set forth in 42 CFR 424.44. Based on recent data related to claim denials, we anticipate some situations where the reasonable and necessary denial of the Part A inpatient admission is issued within 1 calendar year from the dates of service, and therefore hospitals would be able to file the Part B claim timely. Based on the level of billing under Part B as a result of recent ALJ and Medicare Appeals Council decisions, we estimate that approximately 25 percent of the Part A inpatient admissions denied by contractors would result in the submission of a Part B inpatient claim within the timely filing limits.

In addition, we anticipate that hospitals would likely increase their efforts to proactively identify admissions that should be billed under Part B through self-audit, which would decrease the number of Part A inpatient claims submitted, while increasing the number of Part B inpatient claims submitted. Since we do not have data to estimate the number of Part A admissions that hospitals are likely to

self-audit in order to determine if they should be billed under Part B, we are soliciting comments from hospitals regarding the frequency with which self-audits are currently done and the anticipated frequency with which they would self-audit their inpatient admissions to submit Part B claims in a timely manner.

For those cases in which hospitals would not be able to submit a timely Part B claim when the Part A inpatient claim is denied by a Medicare contractor on a post-payment basis, hospitals and beneficiaries may continue to file appeals of the Part A claim denial per 42 CFR part 405 subpart I. We believe the Part B billing provisions proposed in this rule have the potential to lower Part A appeals volume due to the expanded opportunities for billing under Part B. Consequently, we are not anticipating any additional appeals as a result of this proposal. There would be some administrative costs incurred by MACs in verifying there is no pending Part A appeal prior to processing a Part B inpatient claim, but we believe that this would be similar to the existing administrative burden MACs incur with receiving and effectuating the appeal decisions that would have to be processed had the hospitals pursued their Part A appeal.

2. Anticipated Effects on Hospitals

The timely filing restrictions proposed on filing Part B claims will require hospitals to closely monitor the status of Part A claim denials so that they may submit Part B inpatient claims, when appropriate. While the timely filing limits would not always afford hospitals the opportunity to submit Part B claims, hospitals would still have the opportunity to appeal the Part A claim determination if they disagree with the contractor's decision. Also, since a Part B claim can only be processed if there is no pending Part A

appeal, hospitals would be required to request withdrawal of pending appeals if they wish to submit any Part B claims. Hospitals are parties to claim appeals, and will be able to track pending appeals, including beneficiary appeals. They receive copies of decision letters when appeals have been completed, and receive copies of notices of hearing when an appeal gets to the ALJ level. Hospitals may also access the status of a claim appeal at the reconsideration level and hearing level through www.q2a.com by using the Medicare appeal number for the claim.

In addition, hospitals would have to refund amounts collected from the beneficiary (or third party insurer) for denied Part A claims if the hospital is determined to be liable under section 1879 of the Act for the denied items and services furnished to a beneficiary. This is not a new burden, as hospitals are required to make that refund absent any of the proposals in this rule. Hospitals that choose to submit Part B inpatient claims under the proposed process may also need to collect from the beneficiary the applicable deductible and copayment related to covered Part B items and services, and the cost of items excluded from Part B coverage. We believe that the burden to bill a Part B claim and collect any Part B copayments and deductibles is likely similar to or less than the burden hospitals currently face when appealing the denial of the Part A inpatient admission.

E. Alternatives Considered

We proposed that all hospitals and CAHs would be eligible to bill additional Part B inpatient services when a Part A claim is denied because the admission was not reasonable and necessary but hospital outpatient services would have been reasonable and necessary. In section II.D. of this proposed rule, we proposed to require that hospitals currently not billing the OPPS for Part B inpatient services (those

with no outpatient departments, or that have outpatient departments but submit no claims to Medicare Part B) would now bill the OPPTS for these services. We considered allowing these hospitals to continue to bill Part B inpatient services for payment under their pre-OPPS payment methodology consistent with existing policy. We did not propose this

policy because we believe their likely payments under the proposed Part B inpatient policy would outweigh their costs of implementing billing systems specific to the OPPTS.

F. Accounting Statement and Table

Whenever a rule is considered a significant rule under Executive Order

12866, we are required to develop an Accounting Statement. This statement must state that we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. We present this information in Table 3 as follows:

TABLE 3—ACCOUNTING STATEMENT TABLE: CLASSIFICATION OF ESTIMATED MEDICARE AND BENEFICIARIES'-OUT-OF-POCKET EXPENDITURES FOR HOSPITAL SERVICES *

[In millions of 2013 dollars]

Category	Transfers		
	Units discount rate		Period covered
Annualized Monetized Transfers	7% – \$877	3% – \$896	CYs 2013–2017
From/To	Federal Government to Hospitals		
Annualized Monetized Transfers	7% – \$44	3% – \$45	CYs 2013–2017
From/To	Beneficiaries to Hospitals		

* These amounts are based on the conversion to constant year dollars of the 12-month timely filing restriction policy figures in Tables 1 and 2 of this proposed rule.

G. Conclusion

The analysis provided in this section of this proposed rule, together with the remainder of this preamble, provides a Regulatory Impact Analysis. In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

■ 2. Subpart A is amended by adding § 414.5 to read as follows:

§ 414.5 Hospital inpatient services paid under Medicare Part B when a Part A hospital inpatient claim is denied because the inpatient admission was not reasonable and necessary, but hospital outpatient services would have been reasonable and necessary in treating the beneficiary.

(a) If a Medicare Part A claim for inpatient hospital services is denied because the inpatient admission was not reasonable and necessary, or if a hospital determines under § 482.30(d) of this chapter § 485.641 of this chapter after a beneficiary is discharged that the beneficiary's inpatient admission was not reasonable and necessary, the hospital may be paid for any of the following Part B services that would have been reasonable and necessary if the beneficiary had been treated as a hospital outpatient rather than admitted as an inpatient, provided the beneficiary is enrolled in Medicare Part B:

(1) Services described in § 419.21(a) of this chapter that do not require an outpatient status.

(2) Ambulance services, as described in section 1861(v)(1)(U) of the Act, or, if applicable, the fee schedule established under section 1834(l) of Act.

(3) Except as provided in § 419.2(b)(11) of this chapter, prosthetic devices, prosthetics, prosthetic supplies, and orthotic devices.

(4) Except as provided in § 419.2(b)(10) of this chapter, durable medical equipment supplied by the hospital for the patient to take home.

(5) Clinical diagnostic laboratory services.

(6)(i) Effective December 8, 2003, screening mammography services; and (ii) Effective January 1, 2005, diagnostic mammography services.

(7) Effective January 1, 2011, annual wellness visit providing personalized prevention plan services as defined in § 410.15 of this chapter.

(b) The claims for the Part B services filed under the circumstances described in this section must be filed in accordance with the time limits for filing claims specified in § 424.44(a) of this chapter.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 3. The authority citation for part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

■ 4. Section 419.21 is amended by revising the section heading to read as follows:

§ 419.21 Hospital services subject to the outpatient prospective payment system.

* * * * *

■ 5. Section 419.22 is amended as follows:

■ A. Revising the section heading.

■ B. In paragraph (h), by removing the phrase “Outpatient therapy” and adding in its place the term “Therapy”.

■ C. In paragraph (j), removing the cross-reference “§ 419.22(b)(11)” and adding in its place “§ 419.2(b)(11)”.

■ D. Adding paragraph (u).

The revision and addition reads as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

* * * * *

(u) Outpatient diabetes self-management training.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 1, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 7, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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