April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994). This action does not involve technical standards; thus, the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) do not apply. The Congressional Review Act, 5 U.S.C. 801 et seq., generally provides that before certain actions may take effect, the agency promulgating the action must submit a report, which includes a copy of the action, to each House of the Congress and to the Comptroller General of the United States. Because this action does not contain legally binding requirements, it is not subject to the Congressional Review Act.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: March 11, 2013.
Mathy Stanislaus,
Assistant Administrator, Office of Solid Waste and Emergency Response.

For the reasons set out above, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

1. The authority citation for part 300 continues to read as follows:


2. Section 300.805 is amended by revising paragraph (c) to read as follows:

§300.805 Location of the administrative record file.

* * * * * * * * *

(c) The lead agency may make the administrative record file available to the public in microform, computer telecommunications, or other electronic means.

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 411, 412, 419, 424, and 489

[CMS–1455–NR]

Medicare Program; Medicare Hospital Insurance (Part A) and Medicare Supplementary Medical Insurance (Part B)

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

ACTION: Notice of CMS ruling.

SUMMARY: This notice announces a CMS Ruling that establishes a policy that revises the current policy on Part B billing following the denial of a Part A inpatient hospital claim by a Medicare review contractor on the basis that the inpatient admission was determined not reasonable and necessary. This revised policy is intended as an interim measure until CMS can finalize a policy to address the issues raised by the Administrative Law Judge and Medicare Appeals Council decisions going forward. To that end, elsewhere in this issue of the Federal Register, we published a proposed rule entitled, “Medicare Program; Part B Inpatient Billing in Hospitals,” to propose a permanent policy that would apply on a prospective basis.

DATES: The CMS ruling announced in this notice is effective on March 13, 2013.

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, (410) 786–3059, for issues related to general appeals policy. If you have a question about a pending appeal, please contact the entity (that is, Medicare contractor, Qualified Independent Contractor (QIC), Administrative Law Judge (ALJ) or the Appeals Council) where your appeal is pending. For those cases that were remanded from an ALJ to a QIC, HHS’ Office of Medicare Hearings and Appeals (OMHA) will post further information on its public Web site at www.hhs.gov/omha. The contact names listed will not have any information about specific, pending appeals.

SUPPLEMENTARY INFORMATION: The CMS Administrator signed Ruling CMS–1455–R on March 13, 2013. This CMS Ruling, as well as other CMS Rulings are available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/index.html. For the readers’ convenience, the text of the CMS Ruling 1455–R is set forth in the Appendix to this notice of CMS ruling:

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


Marilyn Tavenner,
Acting Administrator, Centers for Medicare & Medicaid Services.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix

CMS Rulings

Department of Health and Human Services

Centers for Medicare & Medicaid Services

Ruling No.: CMS–1455–R.

Date: March 13, 2013.

Centers for Medicare & Medicaid Services (CMS) Rulings are decisions of the Administrator of CMS that serve as precedential final opinions, orders and statements of policy and interpretation. They provide clarification and interpretation of complex provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters. They are published under the authority of the Administrator.

CMS Rulings are binding on all CMS components, Part A and Part B Medicare Administrative Contractors (MACs), Qualified Independent Contractors (QICs), the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, and on the Medicare Appeals Council and Administrative Law Judges (ALJs) who hear Medicare appeals. Rulings promote consistency in interpretation of policy and adjudication of disputes.

In light of numerous recent Medicare Appeals Council and ALJ decisions on a recurrent Medicare payment issue and in association with this Ruling, CMS is concurrently issuing a proposed rule, entitled “Medicare Program; Part B Billing in Hospitals” addressing the policy of billing under Medicare Part B following a denial of a Medicare Part A hospital inpatient claim by a Medicare review contractor for the reason that an inpatient admission was not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act (the Act). This Ruling is effective as of the issuance date, and addresses the treatment of such claims and associated appeals until the effective date of the final regulations for the proposed rule entitled, “Medicare Program; Part B Billing in Hospitals”.

Medicare Program

Medicare Hospital Insurance (Part A) and Medicare Supplementary Medical Insurance (Part B).
Clarification of Billing Under Medicare Parts A and B


Background

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 the 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 Part A claim for payment. Under such circumstances, Medicare payment policy has permitted hospitals to 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. (For more information, see, Internet Only Manual (IOM) Pub. 100–02, Medicare Benefit Policy Manual (MBPM), Chapter 6, Section 10; Prospective Payment System for Hospital Outpatient Services, Proposed Rule, 63 FR 47560 (September 8, 1998) and Final Rule, 65 FR 18444 (April 7, 2000); Changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2002, Proposed Rule, 66 FR 44698 through 44699 (August 24, 2001) and Final Rule, 66 FR 59891 through 59893, and 59915, (November 30, 2001); Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Final Rule (75 FR 73449 and 73627, November 29, 2010). While decisions issued by the Medicare Appeals Council 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. This Ruling establishes a standard process for effectuating these decisions and handling pending claims and appeals in the interim while CMS considers how to best address this issue going forward. The Ruling also addresses the scope of administrative decisions and other similar cases. Until the final regulations entitled, “Medicare Program; Part B Inpatient Billing in Hospitals” are promulgated, CMS, through this Ruling, acquiesces to the approach taken in the aforementioned ALJ and Appeals Council decisions on the issue of subsequent Part B billing following the denial of a Part A hospital inpatient claim on the basis that the admission was not reasonable and necessary. The policy announced in this Ruling supersedes any other statements of policy on this issue and remains in effect until the effective date of the regulations that finalize the proposed rule entitled, “Medicare Program; Part B Inpatient Billing in Hospitals”, which we are issuing concurrently with this Ruling.

Ruling

Part B Hospital Inpatient Billing

In light of the numerous recent ALJ and Medicare Appeals Council decisions previously described, this Ruling establishes a policy that revises the current policy on Part B billing following the denial of a Part A inpatient hospital claim by a Medicare claims review contractor on the basis that the inpatient admission was determined not reasonable and necessary. The revised policy is intended as an interim measure until CMS can finalize a policy to address the issues raised by the ALJ and Medicare Appeals Council decisions going forward. To that end, we issued a proposed rule entitled, “Medicare Program; Part B Inpatient Billing in Hospitals,” today, to propose a permanent policy on a prospective basis once the proposed rule is finalized. Accordingly, this Ruling is effective only until such time as the aforementioned proposed rule is finalized.

To date, under MBPM, Chapter 6, Section 10, a limited set of Part B inpatient services may be paid in the following circumstances:

- The admission was approved 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.

This Ruling applies only in the second circumstance listed previously, that is, when the admission was disapproved as not reasonable and necessary by a Medicare review contractor, and payment for the denied services was not made pursuant to section 1879 of the Act (and provided the hospital’s responsibility for repayment of an overpayment was not waived under section 1870 of the Act). Because the other circumstances for Part B inpatient billing listed in the MBPM are not the subject of the administrative appeals that this Ruling is designed to address (for example, when a beneficiary has no coverage under Part A because he or she exhausts Part A benefits), the existing policy applies in all other applicable circumstances, and a hospital may continue to bill for only the limited set of Part B inpatient services and must do so within the timely filing requirements.

Pursuant to this Ruling, a Part A inpatient claim for a hospital inpatient admission is denied by a Medicare review contractor because the inpatient admission was not reasonable and necessary, the hospital may submit a Part B inpatient claim for more services than just those listed in the MBPM, Chapter 6, Section 10, to the extent additional reasonable and necessary services were furnished. In this case, the hospital may submit a Part B inpatient claim for Part B services that would have been provided 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, for example, outpatient visits, emergency department visits, and observation services. Such services that require an outpatient status cannot be billed for the time period the beneficiary spent in the hospital as an inpatient and cannot be included on the Part B inpatient claim (see the following discussion of patient status).

Three-Day Payment Window Prior to the Inpatient Admission

Current Medicare policy requires payment for certain outpatient services furnished on the date of an inpatient admission or during the 3-calendar days (or 1-calendar day for hospitals not paid under the hospital inpatient prospective payment systems (IPPS)) prior to the date of the inpatient admission (collectively, “the 3-day (or 1-day for non-IPPS hospitals) payment window prior to the inpatient admission”). This Ruling also applies to bills for the inpatient admission bundled with the payment for the inpatient stay. See IOM Pub. 100–04, Medicare Claims Processing Manual (MCPM), Chapter 3, Section 40.3 and Chapter 4, Section 10.12.

Under this Ruling, in cases for which no Part A payment is made because the Part A inpatient claim is denied, that is, that the inpatient admission was not reasonable and necessary, hospitals may bill separately for the outpatient services furnished during the 3-day (or 1-day for non-IPPS hospitals) payment window prior to the inpatient admission as the outpatient services that they were, including observation and other...
services that were furnished in accordance with Medicare’s requirements. Because services provided during the 3-day (or 1-day for non-IPPS hospitals) payment window prior to the denied inpatient admission are outpatient services, these services may not be included on the Part B inpatient claim. Instead, hospitals may bill for these services on a Part B outpatient claim, which, in accordance with the policy announced in this Ruling, will not be subject to the usual timely filing restrictions discussed later in this Ruling. Hospitals may only submit claims for Part B inpatient and Part B outpatient services that are reasonable and necessary in accordance with Medicare coverage and payment rules. Hospitals must maintain documentation to support the services billed on a Part B inpatient claim for services rendered during the inpatient stay, in addition to those billed on a Part B outpatient claim for services rendered in the 3-day (or 1-day for non-IPPS hospitals) payment window prior to the inpatient admission.

**Applicability**

This Ruling is effective on the 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 this Ruling is in effect; (2) prior to the effective date of this Ruling, but for which the timeframe to file an appeal has not expired; or (3) prior to the effective date of this Ruling, but for which an appeal is pending. This Ruling does not apply to Part A hospital inpatient claim denials for which the timeframe to appeal expired prior to the effective date of this Ruling, and it does not apply to inpatient admissions deemed by the hospital to be not reasonable and necessary (for example, through utilization review or other self-audit).

**Treatment of Pending Appeals and Appeal Rights**

We are aware that there are currently thousands of appeals pending that are subject to this Ruling. In determining the least burdensome approach for both hospitals and CMS, we are publishing this Ruling to provide hospitals with notice of their right to withdraw pending appeals of Part A claim denials that are subject to this Ruling, and instead submit Part B claims for payment. Requests for withdrawal of pending Part A claim appeals must be sent to the adjudicator with whom the appeal is currently pending, except where the appeal has been remanded from an ALJ to a QIC. Under this Ruling, appeals of Part A claim denials that were remanded from the ALJ level to the QIC level will be returned to the ALJ level for adjudication of the Part A claim appeal consistent with the scope of review explained later in this Ruling. QICs will send affected hospitals notice regarding this action. The Office of Medicare Hearings and Appeals (OMHA) will provide instructions for submitting requests for withdrawal of ALJ hearings, including cases that were remanded from an ALJ to a QIC. OMHA will post the instructions on its public Web site at www.hhs.gov/omha, or appellants may call any OMHA Field Office (included in the Notice of Hearing sent by an ALJ and on the OMHA Web site) to request a copy of the instructions by mail or facsimile. Until and unless adjudicators receive a request for withdrawal, they will continue processing all pending Part A appeals that are subject to this Ruling.

In order to prevent duplicate billing and payment, a hospital may not simultaneously request for payment under both Parts A and B for the same services provided to a single beneficiary on the same dates of service. Thus, if a hospital chooses to submit a Part B claim for payment following the denial of a Part A inpatient admission, the hospital cannot also maintain its request for payment for the same services on the Part A claim. In this situation, the hospital must either choose to no longer pursue an appeal of the Part A claim denial (and thus, as a practical matter, any determination or appeal decision becomes final or binding), allowing the hospital to submit its Part B claim) or must withdraw any pending appeal request on the Part A claim denial prior to the submission of the Part B claim. The request to withdraw the pending Part A claim appeal must be sent to the entity currently processing such appeal, and the entity will issue a dismissal notice. If a hospital submits a Part B claim for payment without withdrawing its appeal request, the Part B claim for payment may be denied as a duplicate. Once the hospital submits a Part B claim, parties will no longer be able to appeal the Part A claim. However, parties will be able to exercise their appeal rights for the subsequent Part B claim under existing procedures in 42 CFR part 405 subpart I.

If the hospital elects to withdraw its Part A appeal and submit a Part B claim, the hospital will have 180 days from the date of receipt of the appeal dismissal notice to submit the claim. If the appeal of the Part A claim remains pending, the hospital may submit a Part B claim if the Part A appeal is later withdrawn. If the Part A appeal decision becomes final or binding, in which case, as explained later in this Ruling, the hospital will have 180 days from the date of receipt of the final or binding decision, or the date of receipt of the dismissal notice to submit the Part B claim.

**Time Period Within Which a Provider Must Bill**

Consistent with longstanding policy, the filing of Part B inpatient and Part B outpatient claims would be considered new claims subject to the time limits for filing claims described in sections 1814(a)(1), 1835(a), and 1842(b)(3)(B) of the Act, and 42 CFR 424.44. However, as an interim measure until the final rule entitled, “Medicare Program Rebilling in Hospitals” can be issued, we are adopting (although not endorsing) the decisions of the ALJs and the Medicare Appeals Council that subsequent Part B rebilling by a hospital in situations covered by this Ruling is supported by concepts of adjustment billing. Under this approach, 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 corresponding denied Part A inpatient claim was filed timely in accordance with 42 CFR 424.44.

If a hospital with a pending appeal for a Part A claim denial subject to this Ruling withdraws its appeal, it will have 180 days from the date of receipt of the dismissal notice to file its Part B claim(s). If a hospital with a pending appeal for a Part A claim denial subject to this Ruling does not withdraw its appeal, the hospital has 180 days from the date of receipt of the final or binding unfavorable appeal decision (or subsequent dismissal notice) to submit its Part B claim(s). For example, if an appellant receives an unfavorable reconsideration decision but decides not to request a hearing before an ALJ, or the time to request a hearing expires, the reconsideration decision becomes binding, and the Part B claim(s) may be filed within 180 days of the date of receipt of the reconsideration decision. If a hospital receives a denial of a Part A inpatient claim subject to this Ruling for which there is no pending appeal, and the denial is not subsequently appealed, the hospital will have 180 days from the date of receipt of the initial or revised determination on the Part A inpatient claim (that is, the date of the remittance advice) to submit its Part B claim(s). The date of receipt of an initial or revised determination, or an appeal decision or dismissal notice is presumed to be 5 days after the date of such notice or decision unless there is evidence to the contrary.

**Scope of Review for Part A Inpatient Claim Denials**

As noted earlier in this Ruling, a number of recent appeal decisions for Part A inpatient claim denials by a Medicare review contractor have affirmed the denial of the Part A inpatient admission, but ordered that payment be issued as if services were provided at an 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. We note that these decisions are in conflict with existing policy. Thus, we are clarifying in this Ruling that hospitals are solely responsible for billing Part B for services furnished in accordance with 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.
405.1100, and 405.1128.] 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 any issue regarding any potential Part B claim the provider has not yet submitted.

Patient Status Under the Ruling

For the Part B claims billed under this Ruling, the beneficiary’s patient status remains inpatient as of the time of inpatient admission and is not changed to outpatient, because the beneficiary was formally admitted as an inpatient and there is no provision to change a beneficiary’s status after she/he is discharged from the hospital. The beneficiary is considered an outpatient for services billed on the Part B outpatient claim, and is considered an inpatient for services billed on the Part B inpatient claim.

Part A to Part B Rebilling Demonstration

The Part A to Part B Rebilling Demonstration is being terminated. We will communicate to hospitals and contractors the details regarding termination of this Demonstration.

Operational Considerations

We will issue operational and any other applicable regulatory guidance that is necessary to implement this Ruling, including the mechanics of how hospitals should bill for Part B inpatient and Part B outpatient services under this Ruling.

Instructions to Contractors

All Medicare contractors including MACs and QICs must implement and follow this Ruling until such time as CMS addresses these issues further.

Held: Pursuant to this Ruling, when a Part A claim for a hospital inpatient admission is denied by a Medicare review contractor because the inpatient admission was not reasonable and necessary, the hospital may submit a Part B inpatient claim for more services than just those listed in the MBPM, Chapter 6, Section 10, to the extent additional reasonable and necessary services were furnished. In this case, 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 as admitted as an inpatient, except when those services specifically require an outpatient status, for example, outpatient visits, emergency department visits, and observation services. Hospitals must submit their Part B claim within the timeframes specified in this Ruling. Further, where no Part A payment is made because the Part A inpatient claim is denied on the basis that the inpatient admission was not reasonable and necessary, hospitals may continue to bill separately for the outpatient services furnished during the 3-day (or 1-day for non-IPPS hospitals) payment window prior to the inpatient admission, including observation and other services that were furnished in accordance with Medicare’s requirements. In order to prevent duplicate billing and payment, a hospital may not have simultaneous requests for payment under both Parts A and B for the same services provided to a single beneficiary on the same dates of service. Thus, if a hospital chooses to submit a Part B claim for payment following the denial of a Part A inpatient admission, the hospital cannot also maintain its request for payment for the same services on the Part A claim. This Ruling 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 this Ruling is in effect; (2) Prior to the effective date of this Ruling, but for which the timeframe to file an appeal has not expired; or (3) Prior to the effective date of this Ruling, but for which an appeal is pending. This Ruling does not apply to Part A hospital inpatient claim denials for which the timeframe to appeal expired prior to the effective date of this Ruling, and it does not apply to inpatient admissions deemed by the hospital to be not reasonable and necessary (for example, through utilization review or other self-audit). For the Part B claims billed under this Ruling, the beneficiary’s patient status remains inpatient as of the time of inpatient admission and is not changed to outpatient, because the beneficiary was formally admitted as an inpatient and there is no provision to change a beneficiary’s status after she/he is discharged from the hospital. The beneficiary is considered an outpatient for services billed on the Part B outpatient claim, and is considered an inpatient for services billed on the Part B inpatient claim.

Effective Date

This Ruling is effective March 13, 2013. Dated: ____________________________
Marilyn Tavenner,
Acting Administrator, Centers for Medicare & Medicaid Services.

BILLING CODE P

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 11207737–2141–02 and 112113751–2102–02]

RIN 0648–XC569

Fisheries of the Exclusive Economic Zone Off Alaska; Sablefish Managed Under the Individual Fishing Quota Program

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; opening.

SUMMARY: NMFS is opening directed fishing for sablefish with fixed gear managed under the Individual Fishing Quota (IFQ) Program and the Community Development Quota (CDQ) Program. The season will open 1200 hours, Alaska local time (A.l.t.), March 23, 2013, and will close 1200 hours, A.l.t., November 7, 2013. This period is the same as the 2013 commercial halibut fishery opening dates adopted by the International Pacific Halibut Commission. The IFQ and CDQ halibut season is specified by a separate publication in the Federal Register of annual management measures.

DATES: Effective 1200 hours, A.l.t., March 23, 2013, until 1200 hours, A.l.t., November 7, 2013.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION:
Beginning in 1995, fishing for Pacific halibut and sablefish with fixed gear in the IFQ regulatory areas defined in 50 CFR 679.2 has been managed under the IFQ Program. The IFQ Program is a regulatory regime designed to promote the conservation and management of these fisheries and to further the objectives of the Magnuson-Stevens Fishery Conservation and Management Act and the Northern Pacific Halibut Act. Persons holding quota share receive an annual allocation of IFQ. Persons receiving an annual allocation of IFQ are authorized to harvest IFQ species within specified limitations. Further information on the implementation of the IFQ Program, and the rationale supporting it, are contained in the preamble to the final rule implementing the IFQ Program published in the Federal Register, November 9, 1993 (58 FR 59375) and subsequent amendments. This announcement is consistent with § 679.23(g)(1), which requires that the directed fishing season for sablefish managed under the IFQ Program be specified by the Administrator, Alaska Region, and announced by publication in the Federal Register. This method of season announcement was selected to facilitate coordination between the sablefish season, chosen by the Administrator, Alaska Region, and the halibut season, adopted by the International Pacific Halibut Commission (IPHC). The directed fishing season for sablefish with fixed gear managed under the IFQ Program will open 1200 hours, A.l.t., March 23, 2013, and will close 1200 hours, A.l.t., November 7, 2013. This period runs concurrently with the IFQ season for Pacific halibut announced by the IPHC. The IFQ halibut season will be specified by a separate publication in the Federal Register of annual management measures pursuant to 50 CFR 300.62.