• 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 solicited public comment on each of these issues for applicable sections of the Part B Inpatient Billing proposed rule that contained information collection requirements (ICRs) as follows:

With regard to the proposed payment of Medicare Part B inpatient services discussed in section II.B. of the Part B Inpatient Billing proposed rule (and in section XI.B. of the preamble of this final 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 provided 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 the Part B Inpatient Billing proposed rule (and in section XI.B.9. of the preamble of this final rule) is exempt from the requirements of the Paperwork Reduction Act because it is associated with an administrative action (5 CFR 1320.4(a)(2) and (c)).

We did not receive any public comments on these medical recordkeeping requirements or appeals information collection activity.

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

C. Admission and Medical Review Criteria for Hospital Inpatient Services Under Medicare Part A

1. Background

As we discussed in section XI.A. of the preamble of this final rule, in response to concerns about the provision of observation services for increasingly long periods of time albeit in a small percentage of cases, and in response to stakeholders' concerns about the clarity and appropriateness of Medicare's hospital inpatient admission and medical review guidelines, we proposed several clarifications and changes in policy in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27644 through 27650). In this section of this final rule, we discuss the public comments we received in response to our proposals and provide our final policies after consideration of the public comments we received.

2. Requirements for Physician Orders

a. Statutory Basis, Relationship to Physician Certification, and Timing

In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27646 through 27647), we clarified that a beneficiary becomes a hospital inpatient if formally admitted as such pursuant to a physician order for hospital inpatient admission. While the requirement for a physician order for hospital inpatient admission has long been clear in the hospital CoPs, we proposed to state explicitly in our payment regulations that admission pursuant to this order is the means whereby a beneficiary becomes a hospital inpatient and, therefore, is required for payment of hospital inpatient services under Medicare Part A. We stated that a beneficiary becomes a hospital inpatient when admitted as such after a physician (or other qualified practitioner as provided in the regulations) orders inpatient admission in accordance with the CoPs, and that Medicare pays under Part A for such an admission if the order is documented in the medical record. We stated that the order must be supported by objective medical information for purposes of the Part A payment determinations.

Accordingly, we proposed new 42 CFR 412.3(a), which states, ''For purposes of payment under Medicare Part A, an individual is considered an inpatient of a hospital, including a critical access hospital, if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner in accordance with this section and §§ 482.24(c), 482.12(c), and 485.638(a)(4)(iii) of this chapter for a critical access hospital.'' We stated that this physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A (78 FR 27647).

In addition, in the proposed rule, we discussed the statutory requirement for certification of hospital inpatient services for payment under Medicare Part A. The certification requirement for inpatient services other than psychiatric inpatient services is found in section 1814(a)(3) of the Act, which provides that Medicare Part A payment will only be made for such services ''which are furnished over a period of time, [if] a physician certifies that such services are required to be given on an inpatient basis.'' The regulation implementing this requirement is found at 42 CFR 424.13(a).

The requirement for certification and recertification of inpatient psychiatric services as a condition of payment are found in section 1814(a)(2) of the Act and 42 CFR 424.14. We did not propose to exclude any hospitals from our proposed clarification of the requirement for the physician order and physician certification for Part A payment of hospital inpatient services.

Comment: One commenter asked CMS to clarify what is meant by physician ''certification.'' Some commenters believed that CMS did not articulate a statutory authority for requiring the physician order as a condition of Part A payment. The commenters stated that the proposed rule implied that the physician order requirement flows from section 1814(a)(3) of the Act, which sets forth conditions and limitation on payment, one of which is a requirement for a physician certification that inpatient hospital services furnished over a period of time are required on an inpatient basis for such individual's medical treatment. Other commenters assumed that, in the proposed rule, CMS was equating the physician order with the physician certification that is required for payment under section 1814(a)(3) of the Act, stating that in the Social Security Amendments of 1967 to this section of the Act, Congress found that admission ''orders'' are not required for Medicare payment because hospital admissions are almost always medically necessary.

These commenters objected to the proposal to clarify that inclusion of the inpatient admission order in the medical record is a condition of payment. The commenters acknowledged that the hospital CoPs already require as a health and safety measure that the inpatient admission decision be made upon the ''recommendation'' of a physician. However, they believed it would be duplicative to also require an order as a condition of payment, and were concerned that the requirement would become the basis for hospital liability under the False Claims Act. One commenter stated that CMS' proposal crossed the line in dictating the practice

of medicine. Some commenters believed that CMS proposed a new requirement that is not supported in the statute and is contrary to longstanding practice under the Medicare program. These commenters argued that the statutory reference to services furnished ''over a period of time'' as well as the regulation's lack of any specific deadline for physician certifications in nonoutlier cases indicate that no certification is required for short-stay cases.

In support of their argument, the commenters cited the legislative history of section 1814(a)(3) of the Act, which they interpret to apply only to certain long-term stays. They noted that, in the Social Security Amendments of 1967, Congress amended the statutory language from requiring physician certification of hospital inpatient services to requiring physician certification only for ''inpatient hospital services . . . which are furnished over a period of time.'' Moreover, the commenters cited congressional reports [196] explaining this statutory change by stating that it ''eliminate[d] the requirement for hospital insurance payments that there be a physician's certification of medical necessity with respect to admissions to hospitals which are neither psychiatric nor tuberculosis institutions'' and that such a certification is required ''only in cases of hospital stays of extended duration.'' The commenters suggested that the House report also explains the reason for the change, stating that ''admissions to general hospitals are almost always medically necessary and the requirement for a physician's certification of this fact results in largely unnecessary paperwork'' (H.R. Rep. No. 90–544, at 38 (1967)). Based upon all of the above factors, the commenters argued that, since 1967, the agency has not had authority to require a physician order as a condition of payment for hospital inpatient stays other than extended stays.

Response: We do not agree that these arguments mandate the conclusion that the physician certification requirement only applies to long-stay cases. The statute does not define ''over a period of time,'' and further provides that ''such certification shall be furnished only in such cases, and with such frequency, and accompanied by such supporting material . . . as may be provided by regulations.'' By this language, Congress explicitly delegated authority to the agency to elucidate this provision of the statute by regulation. Accordingly, CMS is authorized to interpret the statutory phrase ''over a period of time'' so long as its interpretation is not arbitrary, capricious, or manifestly contrary to statute *(Chevron U.S.A. Inc.* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984)).

Section 424.13 of the regulations does not contain any length-of-time restrictions on the applicability of the certification requirement. Instead, § 424.13(a) provides that Medicare Part A payment will only be made for inpatient hospital services (other than inpatient psychiatric services) if a physician certifies or recertifies ''the need for continued hospitalization of the patient for medical treatment or medically required inpatient diagnostic study.'' Therefore, in its implementing regulations, CMS interpreted the statute's requirement of a physician certification for inpatient hospitals services furnished ''over a period of time'' to apply to all inpatient admissions. While this is not the only possible interpretation of the statute, we believe that it is a permissible interpretation.

We recently reiterated our requirement of a physician order for all inpatient admissions in the preamble to the CY 2012 Medicare Physician Fee Schedule final rule. In a discussion regarding whether services furnished to a patient who is at the hospital overnight, but for less than 24 hours, should be billed as outpatient or inpatient services, CMS stated that ''[u]nless a treating physician has written an order to admit the patient as an inpatient, the patient is considered for Medicare purposes to be a hospital outpatient, not an inpatient'' (76 FR 73106). In addition, the CoPs illustrate that CMS' policy requires a physician order in order to justify inpatient hospitalization (including inpatient psychiatric hospitalizations). Under 42 CFR 482.12(c)(2), a hospital's governing body must ensure that ''[p]atients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital.'' In addition, § 482.24(c) requires that a patient's medical record ''contain information to justify admission and continued hospitalization.''

We also have indicated our current policy and its applicability to all types of hospitals in our subregulatory guidance. In the MBPM, Chapter 1, Section 10, we define an inpatient as ''a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient services.'' This section further explains that ''[g]enerally, a patient is considered an inpatient if formally admitted as inpatient with an expectation that he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight.'' In addition, Section 10 provides that ''[t]he physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient.''

CMS' policy is also reflected in the Medicare Claims Processing Manual (MCPM) (Pub. 100–04), Chapter 3, Section 40.2.2(K), which discusses the circumstance where a patient is admitted to an inpatient hospital, but dies or is discharged before being assigned to a room. Certainly, this circumstance would not qualify as a long stay, but CMS still requires a physician order to justify the admission, stating that ''[a] patient of an acute care hospital is considered an inpatient upon issuance of written doctor's orders to that effect.'' Finally, Chapter 4 of the Medicare General Information, Eligibility, and Entitlement Manual also addresses the certification requirement. Section 10 of Chapter 4 provides that ''[p]ayments may be made for covered hospital services only if a physician certifies and recertifies to the medical necessity for the services at designated intervals of the hospital inpatient stay.'' As members of the hospital community have noted in the past, this section also states that ''[f]or patients admitted to a general hospital . . . a physician certification is not required at the time of admission.'' However, this merely means that the certification need not be contemporaneous with the admission, rather than indicating that no certification is required.

Therefore, our longstanding policy, as reflected in our regulations and other guidance, has been that a physician order is required for all inpatient hospital admissions, regardless of the length of stay. We believe that this policy is a legally supportable interpretation of section 1814(a) of the Act. In order to clarify this policy going forward, we are finalizing § 412.3(a) to include the proposed language as well as the provision we described in the proposed rule (78 FR 27647) that the order must be present in the medical record and supported by the physician admission and progress notes. We are adding this preamble language from the proposed rule to the regulation text to improve clarity and provide consistency with our policy on medical review of inpatient admissions (section XI.C.3. of the preamble of this proposed rule) that,

[196] S. Rep. No. 90–744, at 239 (1967), H.R. Rep. No. 90–544, at 149 (1967).

while the physician order and the physician certification are required for all inpatient hospital admissions in order for payment to be made under Part A, the physician order and the physician certification are not considered by CMS to be conclusive evidence that an inpatient hospital admission or service was medically necessary. Rather, the physician order and physician certification are considered along with other documentation in the medical record.

As finalized, § 412.3(a) reads: ''For purposes of payment under Medicare Part A, an individual is considered an inpatient of a hospital, including a critical access hospital, if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner in accordance with this section and §§ 482.24(c), 482.12(c), and 485.638(a)(4)(iii) of this chapter for a critical access hospital. This physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A. In addition to these physician orders, inpatient rehabilitation facilities also must adhere to the admission requirements specified in § 412.622 of this chapter.'' (We discuss the application of these final policies to IRFs in section XI.C.2.c. of the preamble of this final rule.)

To provide further clarity and to more closely mirror the authorizing statutory language, we are deleting the word ''continued'' and adding the word ''inpatient'' before the phrase ''medical treatment'' in § 424.13(a)(2), to reflect that the content of the certification of inpatient services (other than inpatient psychiatric services) includes the reason for inpatient hospital services. The amended paragraph reads, ''(a) *Content of certification and recertification.* Certification begins with the order for inpatient admission. Medicare Part A pays for inpatient hospital services (other than inpatient psychiatric facility services) only if a physician certifies and recertifies the following:

(1) That the services were provided in accordance with § 412.3 of this chapter

(2) The reasons for either—

(i) Hospitalization of the patient for inpatient medical treatment or medically required inpatient diagnostic study; or

(ii) Special or unusual services for cost outlier cases (under the prospective payment system set forth in subpart F of Part 412 of this chapter).''

We believe this language better reflects the statutory content of the certification required by section 1814(a)(3) of the Act ''[t]hat such services are required to be given on an inpatient basis for such individual's medical treatment, or that inpatient diagnostic study is medically required and such services are necessary for such purpose.''

We note that the particular elements of the certification, for example, the order for inpatient services and documentation of the reason for continued hospitalization (diagnosis) should be documented within the medical record. Therefore, we are not finalizing any new documentation requirements. The existing provisions in § 424.11 continue to apply, for example paragraphs (b) and (c) which provide that no specific procedures or forms are required for certification and recertification statements. The provider may adopt any method that permits verification. The certification and recertification statements may be entered on forms, notes, or records that the appropriate individual signs, or on a special separate form. Except as provided for delayed certifications, there must be a separate signed statement for each certification or recertification. The succeeding sections of Part 424, subpart B set forth specific information required for different types of services. If that information is contained in other provider records, such as physicians' progress notes, it need not be repeated. It will suffice for the statement to indicate where the information is to be found.

To clarify the relationship between the physician order and the physician certification, we are adding new 42 CFR 412.3(c) which states that ''The physician order also constitutes a required component of the physician certification of the medical necessity of hospital inpatient services under Part 424 of this chapter.'' Similarly, we are revising paragraph (a) of § 424.13 to include in the content of the certification for inpatient hospital services (other than inpatient psychiatric services): ''(1) [t]hat the services were provided in accordance with § 412.3 of this chapter [the order].'' We are adding parallel provisions in 42 CFR 424.14(b) and 424.15(a) to include in the content of the physician certification for payment of inpatient psychiatric services and inpatient CAH services, respectively, that the services were provided in accordance with § 412.3. We discuss additional rules for certification that apply to inpatient services furnished in IRFs in section XI.C.2.c. of the preamble of this final rule.

To further clarify the relationship between the physician order and the physician certification, and our requirement that, like the order, the certification applies to all hospital inpatient admissions (not just extended stays), we are adding new provisions to the regulations regarding timing of the certification. In § 424.13, we are providing that the certification must be signed and documented in the medical record prior to the hospital discharge (except for recertifications of extended stays, which are required earlier). We are redesignating existing paragraphs (b) through (g) of § 424.13 as paragraphs (c) through (h), respectively, in order to add a new paragraph (b). We are requiring under new § 424.13(b) that, for inpatient services other than inpatient psychiatric services: ''For all hospital inpatient admissions, the certification must be completed, signed, and documented in the medical record prior to discharge. For outlier cases under subpart F of Part 412 of this chapter that are not subject to the PPS, the certification must be signed and documented in the medical record and as specified in paragraphs (e) through (h) of this section.''

For inpatient psychiatric services, we are adding the phrase ''and must be completed and documented in the medical record prior to discharge'' at the end of § 424.14(d)(1) so that the paragraph reads, ''Certification is required at the time of admission or as soon thereafter as is reasonable and practicable, and must be completed and documented in the medical record prior to discharge.'' We will continue to provide under paragraph (d)(2) of § 424.14 that the first recertification is required as of the 12th day of hospitalization. Subsequent recertifications are required at intervals established by the utilization review committee (on a case-by-case basis if it so chooses), but no less frequently than every 30 days.

Like other components or elements of the physician certification, the physician order reflects affirmation by the ordering practitioner that hospital inpatient services are medically necessary. However, the order serves the unique purpose of initiating the inpatient admission and documenting the physician's (or other qualified practitioner as provided in the regulations) intent to admit the patient, which impacts its required timing. Therefore we are specifying in new paragraph (d) of § 412.3 that ''The physician order must be furnished at or before the time of the inpatient admission'' (unlike the rest of the certification which may be completed prior to discharge, except for the outlier

extended stays described in § 424.13(e) through (g)). Similarly, we are providing in the regulations on the certification that the certification begins with the order for inpatient admission. We are adding this as the new first sentence in §§ 424.13(a), 424.14(a), and 424.15(b) for CAHs. Also, we are including a conforming amendment in new paragraph (d)(5) of § 424.11 that, for hospital or CAH hospital inpatient services, a delayed certification may not extend past discharge. The existing delayed certification provisions in existing § 424.11(d)(3) and (d)(4) will continue to apply, but only for certification of the outlier extended stay cases described in § 424.13(e) through (g).

To clarify that the rules for timing of certification and recertification for ''cases not subject to the PPS'' in redesignated paragraphs (e) through (h) of § 424.13 apply only to IPPS outlier cases, we are adding the word ''outlier'' prior to the phrase ''subject to the PPS'' in paragraphs (e), (f), (g), and (h).

We are finalizing two conforming amendments in the regulation text governing physician certification. In § 424.11(e)(2), we are removing the reference ''§ 424.13(c)'' and adding in its place ''§ 424.13(d)'' as redesignated. Similarly, we are amending § 424.16(a) by removing the reference ''§ 424.13(e)'' and adding it its place ''subpart B of this Part''.

Comment: Several commenters asked what Medicare's payment rules would be regarding verbal inpatient admission orders. For example, the commenters asked whether the hospital could submit a Part A claim based upon a verbal order that is not documented in the medical record at the time the claim is submitted. In addition, the commenters asked how CMS defines ''prompt'' authentication of orders, or address verbal order ''read-back'' processes.

Response: Because the physician order is required as a condition of payment, if the order is not documented in the medical record, the hospital should not submit a claim for Part A payment. A verbal order is a temporary administrative convenience for the physician and hospital staff but it is not a substitute for a properly documented and authenticated order for inpatient admission. A verbal order must be properly countersigned by the practitioner who gave the verbal order. We intend to further discuss and develop our requirements regarding verbal orders for inpatient admission in our subregulatory guidance. The CoPs regarding verbal orders were carefully developed over a period time, and we believe we should take additional time to consider and potentially coordinate the CoP and payment rules.

Comment: Some commenters believed that, while the order should be documented in the medical record as a best practice, documentation of the order should not be required if it is unintentionally omitted. They believed that the order is a technicality that should not serve as a condition of payment. The commenters stated that if the order to admit is missing, yet the physician intent and physician recommendation to admit to inpatient can clearly be derived from the medical record, for example if a medically necessary inpatient-only service was furnished, the contractor should consider these rather than requiring the physician order as a technical requirement for medical necessity and payment.

Response: The admission order is evidence of the decision by the physician (or other practitioner who can order inpatient services) to admit the beneficiary to inpatient status. In very rare circumstances, the order to admit may be missing or defective (that is, illegible or incomplete), yet the intent, decision, and recommendation of the physician (or other practitioner who can order inpatient services) to admit the beneficiary as an inpatient can clearly be derived from the medical record. In these rare situations, we have provided contractors with discretion to determine that this information constructively satisfies the requirement that the hospital inpatient admission order be present in the medical record. However, in order for the documentation to provide acceptable evidence to support the hospital inpatient admission, thus satisfying the requirement for the physician order, there can be no uncertainty regarding the intent, decision, and recommendation by the physician (or other practitioner who can order inpatient services) to admit the beneficiary as an inpatient, and no reasonable possibility that the care could have been adequately provided in an outpatient setting. This narrow and limited alternative method of satisfying the requirement for documentation of the inpatient admission order in the medical record should be extremely rare, and may only be applied at the discretion of the medical review contractor. Even in those circumstances, all requirements for the other components of the physician certification must be met.

Comment: Several commenters asked CMS to clarify whether, when a beneficiary would become an inpatient under the proposed policies, inpatient status would be conferred retroactive to the beginning of the hospital stay. One commenter recommended that the patient become inpatient after the physician writes the order and the patient starts receiving care based on those orders, whether or not it is in a bed on an inpatient nursing unit, a holding bed in the emergency department or another location, or whether the patient is sent to imaging or the operating room first. One commenter questioned what CMS meant by the term ''outpatient status.'' Another commenter questioned CMS' current definition of ''inpatient,'' stating it is not defined in the Act. The commenter stated that, at the time of the law's passage, the meaning of ''inpatient'' was obvious and universal. The commenter stated that a patient that stays in a hospital is an inpatient, whereas a patient that goes home after treatment, or after a limited recovery period such as a few hours, is an outpatient.

Response: As explained in the proposed rule, in response to concerns and suggestions of stakeholders, we aimed to provide more clarity regarding hospital inpatient admissions and Medicare payment. Toward those ends, in the FY 2014 IPPS/LTCH PPS proposed rule, we addressed medical review criteria and proposed to codify in regulation our longstanding policy (as reflected in manual provisions) that a patient becomes an inpatient when formally admitted as such pursuant to a physician order. CMS' definition of ''inpatient'' has been upheld in litigation. *Landers v. Leavitt,* 545 F.3d 98 (2d Cir. 2008). We did not propose policy changes regarding the definition of ''inpatient'' or inpatient status. In contrast to a hospital inpatient, we have defined a hospital outpatient in the MBPM, Chapter 6, Section 20, as ''a person who has not been admitted by the hospital as an inpatient but is registered on the hospital records as an outpatient and receives services (rather than supplies alone) from the hospital or CAH.''

This final rule provides that a beneficiary is considered a hospital inpatient following formal admission ''pursuant to'' the hospital inpatient admission order. We included the phrase ''pursuant to'' in recognition that, in most cases, the beneficiary is formally admitted and becomes a hospital inpatient concurrent with the physician order to admit to inpatient. However, in cases such as elective surgeries where the inpatient admission order is written as far as several weeks in advance, the beneficiary is not considered an inpatient until the time of formal admission at the hospital for the

inpatient services. In this example, the beneficiary is admitted and becomes an inpatient pursuant to the physician's order and could not be admitted without it, although there may be a time lag between when the order to admit is written and the time of formal admission. The physician order cannot be effective retroactively. In this final rule, we are not changing our definition of a ''hospital inpatient.'' Inpatient status only applies prospectively, starting from the time the patient is formally admitted pursuant to a physician order for inpatient admission, in accordance with our current policy.

Comment: Several commenters expressed the opinion that physicians should not have to divide their attention between providing patient care and understanding Medicare's admission rules, which the commenters viewed as mere billing distinctions. Some commenters believed that CMS should allow physicians to delegate the determination of patient status to the hospital or its utilization review committee, while the physician focuses on ordering and providing the necessary clinical care. Further, some commenters stated that this is their current practice. Some commenters commented that their current processes provide for admission ''to case management'' or ''to utilization review'' rather than specifying inpatient admission.

Response: As we discussed above, many public comments from physicians indicated that they believed the physician should be involved in the determination of patient status, and we agree. To reinforce this policy and reduce confusion among hospitals, beneficiaries, and physicians on the differences between outpatient observation and inpatient services, we are providing in this final rule that the order for inpatient admission must specify admission ''to or as an inpatient.'' In previous discussions, stakeholders have indicated that often physician orders only specify admission to a certain location in the hospital (for example, ''Admit to Tower 7'') or do not clarify whether the physician's intent is to ''admit'' the beneficiary for outpatient observation services or for hospital inpatient services. Therefore, we are providing that, for payment of hospital inpatient services under Medicare Part A, the order must specify the admitting practitioner's recommendation to admit ''to inpatient,'' ''as an inpatient,'' ''for inpatient services,'' or similar language specifying his or her recommendation for inpatient care. In addition, as discussed in the proposed rule (78 FR 27646), we remind hospitals that patients are admitted to the hospital only on the recommendation of a physician or licensed practitioner permitted by the State to admit patients to a hospital, provided that the practitioner, either a physician or other licensed practitioner, has been granted such privileges by the hospital to do so. Hospitals and physicians routinely must work together to comply with billing, coding, and admission rules not just for Medicare, but also for Medicaid and private payers.

b. Authorization to Sign the Physician Order

We proposed new regulation provisions in 42 CFR 412.3(b) which state that, as a condition of payment, the order must be furnished by a qualified and licensed practitioner who has admitting privileges at the hospital as permitted by State law, and who is responsible for the inpatient care of the patient at the hospital. The practitioner could not delegate the decision (order) to another individual who is not responsible for the care of that patient, is not authorized by the State to admit patients, or has not been granted admitting privileges applicable to that patient by the hospital's medical staff.

Comment: Commenters in the physician and Medicare contractor medical review communities generally supported the proposal to require the inpatient admission order, and to provide that it could not be delegated to another individual who does not possess the authority to order inpatient admission in his or her own right. In addition, some commenters representing hospitals did not object to this requirement because it is already standard practice. However, the commenters described a number of situations in which the ordering practitioner would appropriately not be the individual who takes responsibility for the inpatient care of the beneficiary, or for the entirety of the inpatient care. According to the commenters, these included emergency department physicians, hospitalists and other types of physicians in group practices who care for patients in the hospital, and residents working under the supervision of attending physicians. The commenters requested that if CMS finalizes a requirement for the inpatient order as a condition of Part A payment, CMS should allow it to be issued by any physician in the hospital who is knowledgeable about the beneficiary's condition and has admitting privileges at the hospital.

Response: We agree with the commenters that it would be appropriate to allow practitioners who may not be responsible for the inpatient hospital care of the beneficiary but are otherwise qualified to admit patients at that hospital and are knowledgeable about the case to order the inpatient admission. Therefore, we are deleting the proposed language in paragraph (b) of § 412.3 that would have required the order to be issued by a practitioner who is responsible for the inpatient care of the patient at the hospital. We are replacing this language with new language to specify that, although the ordering practitioner need not be responsible for the patient's inpatient care, he or she must be knowledgeable about the patient's hospital course, medical plan of care, and current condition.

We are finalizing all of the other proposed qualifications in paragraph (b) of § 412.3 for the ordering practitioner. The final language reads, ''(b) The order must be furnished by a qualified and licensed practitioner who has admitting privileges at the hospital as permitted by State law, and who is knowledgeable about the patient's hospital course, medical plan of care, and current condition. The practitioner may not delegate the decision (order) to another individual who is not authorized by the State to admit patients, or has not been granted admitting privileges applicable to that patient by the hospital's medical staff.'' We discuss the application of these final policies to IRFs in section XI.C.2.c . of the preamble of this final rule.

c. Applicability to Inpatient Rehabilitation Facilities (IRFs)

We note that IRFs that are excluded from the IPPS and paid under the IRF prospective payment system (IRF PPS) specified in 42 CFR 412.1(a)(3) have certain requirements in 42 CFR 412.622(a)(3), (a)(4), and (a)(5) that govern an inpatient admission to an IRF. These requirements specify the admission criteria that must be documented in the medical record for an IRF admission of a Medicare Part A fee-for-service beneficiary to be considered reasonable and necessary under section 1862(a)(1) of the Act. For example, the documentation requirements contained in these regulations specify that a comprehensive preadmission screening must be conducted and must serve as the basis for the initial determination of whether or not the patient meets the requirements for admission to an IRF. A rehabilitation physician, defined as a licensed physician with specialized training and experience in rehabilitation, must document that he or she has reviewed and concurs with the preadmission screening prior to the

admission. However, we note that Chapter 1, Section 110.1.4 of the MBPM also specifies that, at the time each Medicare Part A fee-for-service patient is admitted to an IRF, a physician must generate admission orders for the patient's care.

Therefore, although the required physician orders discussed in section XI.C.2.a. of the preamble of this final rule apply to all inpatient hospital admissions, including inpatient admissions to an IRF, they do not determine the timing of an IRF admission, nor are they used to determine whether the IRF admission was reasonable and necessary. These determinations are governed by the requirements in §§ 412.622(a)(3), (4), and (5) of the regulations. To clarify this, we have included a provision under new § 412.3 in this final rule that the IRF requirements at § 412.622 also must be met in order for the IRF to be paid for hospital inpatient services under Medicare Part A. However, due to the aforementioned inherent differences in the operation of and beneficiary admission to IRFs, such providers are excluded from the 2-midnight admission guidelines and medical review instruction, as provided under XI.C.3. of the preamble of this final rule.

3. Inpatient Admission Guidelines

CMS is authorized under section 1893 of the Act to implement the Medicare Integrity Program to conduct medical review of claims and ensure appropriateness of Medicare payment. Medicare review contractors, such as Medicare Administrative Contractors (MACs), Recovery Auditors (formerly known as the Recovery Audit Contractors, or RACs), the Comprehensive Error Rate Testing (CERT) Contractor, and other review contractors are hired by CMS to review claims on a pre-payment or post-payment basis to determine whether a claim should be paid or denied or whether a payment was properly made under Medicare payment rules. Following documentation reviews, many claim denials are made or improper payments identified because either—

- The claim was incorrectly coded (for example, the provider did not appropriately assign the individual or grouper inpatient and/or outpatient coding for the care documented); or
- The services were not medically necessary (that is, the review indicates that the services billed were not reasonable and necessary based upon Medicare payment policies or that the documentation was insufficient to support the medical necessity of the services billed).

CMS developed the CERT program to calculate the annual Medicare FFS program improper payment rate. The CERT program considers any claim that was paid when it should have been denied or paid at another amount (including both overpayments and underpayments) to be an improper payment. Hospital claim errors are identified more frequently for shorter lengths of stay. In 2012, the CERT contractor found that Medicare Part A inpatient hospital admissions for 1-day stays or less had an improper payment rate of 36.1 percent. The improper payment rate decreased significantly for 2-day or 3-day stays, which had improper payment rates of 13.2 percent and 13.1 percent, respectively. The improper payment rate further decreased to 8 percent for those beneficiaries who were treated as hospital inpatients for 4 days.

Hospital claim errors are identified more frequently for shorter lengths of stay. The majority of improper payments under Medicare Part A for short-stay inpatient hospital claims have been due to inappropriate patient status (that is, the services furnished were reasonable and necessary, but should have been furnished on a hospital outpatient, rather than hospital inpatient, basis). Inpatient hospital short-stay claim errors are frequently related to minor surgical procedures or diagnostic tests. In such situations, the beneficiary is typically admitted as a hospital inpatient after the procedure is completed, monitored overnight as an inpatient, and discharged from the hospital in the morning. Medicare review contractors typically find that while the underlying services provided were reasonable and necessary, the inpatient hospitalization following the procedure was not (that is, the services following the procedure should have been provided on an outpatient basis).

In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27644 through 27650), we sought to clarify our longstanding policy on how Medicare review contractors review inpatient hospital admissions for payment under Medicare Part A. We also issued proposed guidance to physicians and hospitals regarding when a hospital inpatient admission should be ordered for Medicare beneficiaries. In this final rule we discuss the public comments we received in response to our proposals relating to admission guidance and medical review and provide our final policies after considerations of those public comments.

a. Correct Coding Reviews

We did not propose any changes to coding review strategies for hospital claims. Reviewers will continue to ensure that the correct codes were applied and are supported by the medical record documentation.

b. Complete and Accurate Documentation

When conducting complex medical review, we proposed that Medicare review contractors would continue to employ clinicians to review practitioner documented procedures and ensure that they are supported by the submitted medical record documentation. Such has been the case for complex medical review as historically performed, and will continue to be the case per this final rule instruction.

c. Medical Necessity Reviews

(1) Physician Order and Certification

In the proposed rule (78 FR 27647), we proposed to codify in 42 CFR 412.46(b) the longstanding requirement that medical documentation must support the physician's order and certification, as prescribed by CMS Ruling 93–1. Under the proposed new paragraph (b) titled ''Physician's order and certification regarding medical necessity,'' CMS reiterated that ''No presumptive weight shall be assigned to the physician's order under § 412.3 or the physician's certification under Subpart B of Part 424 of this chapter in determining the medical necessity of inpatient hospital services under section 1862(a)(1) of the Act. A physician's order and certification will be evaluated in the context of the evidence in the medical record.'' We also stated that current requirements for practitioner documentation of services ordered and furnished would remain unchanged. That is, while the physician order and the physician certification are required for all inpatient hospital admissions in order for payment to be made under Part A, the physician order and the physician certification are not considered by CMS to be conclusive evidence that an inpatient hospital admission or service was medically necessary. Rather, the physician order and physician certification are considered along with other documentation in the medical record.

Comment: Some commenters disagreed with the proposal for reviewing the physician order and certification in accord with the documentation in the medical record. Rather, the commenters suggested that an assumption of medical necessity for the inpatient stay would more

appropriately stem from the physician order to admit to inpatient, particularly due its requirement for admission purposes.

Response: Satisfying the requirements regarding the physician order and certification alone does not guarantee Medicare payment. Rather, in order for payment to be provided under Medicare Part A, the care must also be ''reasonable and necessary,'' as specified under section 1862(a)(1) of the Act. In addition, section 1869(a) of the Act provides that determinations regarding entitlement to benefits are under the authority of the Secretary. As stated in our proposed rule, the instruction for reviewers to account for all documentation in the medical record, in addition to the actual order for inpatient admission, is consistent with statutory instruction and our prior policy as outlined in Medicare Ruling 93–1, and is being codified for transparency and consistency.

Comment: Commenters requested that CMS define what constitutes ''objective medical information,'' which is required to support the order for a hospital inpatient admission.

Response: We appreciate the commenters' suggestions that additional documentation guidelines would be helpful. We will consider them as we develop implementation instructions and manual revisions.

(2) Inpatient Hospital Admission Guidelines

In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27648), we indicated that longstanding Medicare policy has recognized that there are certain situations in which a hospital inpatient admission is rarely appropriate. We have stated in the MBPM that when a beneficiary receives a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for only a few hours (less than 24), the services should be provided as outpatient hospital services, regardless of the hour the beneficiary comes to the hospital, whether he or she uses a bed, and whether he or she remains in the hospital past midnight (Section 10, Chapter 1 of the MBPM). In applying this benchmark, we have been clear that this instruction does not override the clinical judgment of the physician to keep the beneficiary at the hospital, to order specific services, or to determine appropriate levels of nursing care or physical locations within the hospital. Rather, this instruction provided a benchmark to ensure that all beneficiaries received consistent application of their Part A benefit to whatever clinical services were medically necessary.

Due to persistently large improper payment rates in short-stay hospital inpatient claims, and in response to requests to provide additional guidance regarding the proper billing of those services, we proposed to modify and clarify our general rule and provide at § 412.3(c)(1) that, in addition to services designated by CMS as inpatient only (which are appropriate for inpatient admission without regard to duration of care), surgical procedures, diagnostic tests, and other treatments would be generally appropriate for inpatient admission and inpatient hospital payment under Medicare Part A when the physician expects the beneficiary to require a stay that crosses at least 2 midnights and admits the beneficiary to the hospital based upon that expectation. Conversely, when a beneficiary enters a hospital for a surgical procedure not specified by Medicare as inpatient only under § 419.22(n), a diagnostic test, or any other treatment, and the physician expects to keep the beneficiary in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A. This would be the case regardless of the hour that the beneficiary came to the hospital or whether the beneficiary used a bed.

In the proposed rule, we provided inpatient hospital admission guidance specifying that a physician or other qualified practitioner (herein we will refer to the physician, with the understanding that this can also pertain to another qualified practitioner) should order admission if he or she expects that the beneficiary's length of stay will exceed a 2-midnight benchmark or if the beneficiary requires a procedure specified as inpatient-only under § 419.22. We proposed that the starting point for this 2-midnight instruction would be when the beneficiary is moved from any outpatient area to a bed in the hospital in which additional hospital services would be provided. We also sought public comment regarding alternative methods of calculating the start time for the 2-midnight instruction.

In the proposed rule, we stated that the judgment of the physician and the physician's order for inpatient admission should be based on the expectation of care surpassing 2 midnights, with both the expectation of time and the determination of the underlying need for medical care at the hospital supported by complex medical factors such as history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. We also indicated that, in accordance with current policy, factors that may result in an inconvenience to a beneficiary or family would not justify an inpatient hospital admission. The factors that lead a physician to admit a particular beneficiary based on the physician's clinical expectation are significant clinical considerations and must be clearly and completely documented in the medical record. Because of the relationship that develops between a physician and his or her patient, the physician is in a unique position to incorporate complete medical evidence in a beneficiary's medical records, and has ample opportunity to explain in detail why the expectation of the need for care spanning at least 2 midnights was appropriate in the context of that beneficiary's acute condition. We stated in the proposed rule that a reasonable expectation of a stay crossing 2 midnights, which is based on complex medical factors and is documented in the medical record, will provide the justification needed to support medical necessity of the inpatient admission, regardless of the actual duration of the hospital stay and whether it ultimately crosses 2 midnights. As such, we acknowledged in the proposed rule that there may be an unforeseen circumstance that results in a shorter beneficiary stay than the physician's expectation of surpassing 2 midnights. We stated that we would expect that the majority of such inpatient hospital admissions would occur when an inpatient hospital admission is appropriately ordered, but a beneficiary's transfer or death interrupts the beneficiary's hospital stay that would have otherwise spanned at least 2 midnights. Therefore, we provided in proposed § 412.3(c)(2), that ''If an unforeseen circumstance, such as beneficiary death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least 2 midnights, the patient may be considered to be appropriately treated on an inpatient basis, and the hospital inpatient payment may be made under Medicare Part A.'' We indicated that documentation in the medical record of such a circumstance would be required for purposes of supporting whether the inpatient hospital admission was reasonable and necessary for Medicare Part A payment. In addition, we explained that the physician must certify that inpatient hospital services were medically necessary in accordance with section 1814(a) of the Act and 42 CFR Part 424, Subpart B.

Comment: Commenters pointed to CMS' guidance that time should not be the leading factor in the decision to admit a beneficiary and that the decision should rely on the physician's clinical judgment and evaluation of the beneficiary's needs based on the severity of illness, the intensity or complexity of care, and the predictability of high-risk adverse outcomes. The commenters stated that there are many beneficiaries who stay in a hospital for less than 2 midnights but still require an inpatient level of care.

Response: In our existing guidance, we stated that the decision to admit a patient as an inpatient is a complex medical decision based on many factors, including the risk of an adverse event during the period considered for hospitalization, and an assessment of the services that the beneficiary will need during the hospital stay. The crux of the medical decision is the choice to keep the beneficiary at the hospital in order to receive services or reduce risk, or discharge the beneficiary home because they may be safely treated through intermittent outpatient visits or some other care. Our previous guidance also provided for a 24-hour benchmark, instructing physicians that, in general, beneficiaries who need to stay at the hospital less than 24 hours should be treated as outpatients, while those requiring care greater than 24 hours may usually be treated as inpatients. Our proposed 2-midnight benchmark, which we now finalize, simply modifies our previous guidance to specify that the relevant 24 hours are those encompassed by 2 midnights. While the complex medical decision is based upon an assessment of the need for continuing treatment at the hospital, the 2-midnight benchmark clarifies when beneficiaries determined to need such continuing treatment are generally appropriate for inpatient admission or outpatient care in the hospital.

Contrary to the commenters' suggestion, we do not refer to ''level of care'' in guidance regarding hospital inpatient admission decisions. Rather, we have consistently provided physicians with the aforementioned time-based admission framework to effectuate appropriate inpatient hospital admission decisions. This is supported by recent findings by the Office of Inspector General (OIG) (OIG, *Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries,* OEI–02–12–00040, July 2013). The OIG found that the reasons for short inpatient stays and for outpatient observation stays were often the same. They further noted that the relative use of short inpatient stays versus outpatient observation stays varied widely between hospitals, consistent with medical review findings that identical beneficiaries may receive identical services as either inpatients or outpatients in different hospitals. We believe that this supports our proposed continuation of our existing policy that there are no prohibitions against a patient receiving any individual service as either an inpatient or an outpatient, except for those services designated by the Outpatient Prospective Payment System (OPPS) Inpatient-Only list as inpatient-only services. We further believe that this supports our proposed policy that the physician is expected to continue to use his or her complex clinical judgment in determining whether a beneficiary needs to stay at the hospital, what services and level of nursing care (for example, low-level, monitored, or one-on-one) the beneficiary will need, and what location (unit) is most appropriate. This does not require that the physician memorize complex billing or utilization guidelines; rather, the physician should generally order an inpatient admission when he or she has determined either that the beneficiary requires care at the hospital that is expected to transcend at least 2 midnights or that it will involve a procedure designated by the OPPS Inpatient-Only list as an inpatient-only procedure.

Comment: Commenters asserted that making a time-based prediction is difficult for the physician. They stated that making such a determination is contradictory to medical professionals' training, which is centered on the assessment of patients and the development of treatment plans, as opposed to focusing on the utilization review process. The commenters also stated that predicting length of stay is difficult because individual patients respond differently to care provided. Commenters suggested that a physician often does not have enough information about a patient at the onset of treatment to make an informed decision regarding anticipated length of stay. For example, a hospitalist admitting a beneficiary through the emergency department likely will not be familiar with the patient and may not have access to extensive medical history documentation on which to make a decision. Commenters suggested that beneficiaries with unknown or uncertain diagnoses should be kept under observation status until their diagnosis and course of treatment become clear. At that point, the commenters added, the hospital would be in the best position to determine the length of treatment, make the decision to admit to inpatient status, or discharge the patient home.

Response: It has been longstanding Medicare policy to require physicians to admit a beneficiary as a hospital inpatient based on their expected length of stay. However, we recognized when we published our definition of observation services that long-term predictions are inherently more difficult than short-term predictions. Therefore, we revised our guidance to indicate that, when it was difficult to make a reasonable prediction, the physician should not admit the beneficiary but should place the beneficiary in observation as an outpatient. As new information becomes available, the physician must then reassess the beneficiary to determine if discharge is possible or if it is evident that an inpatient stay is required. We believe that this principle still applies and have reiterated this in the final rule. For those hospital stays in which the physician cannot reliably predict the beneficiary to require a hospital stay greater than 2 midnights, the physician should continue to treat the beneficiary as an outpatient and then admit as an inpatient if and when additional information suggests a longer stay or the passing of the second midnight is anticipated.

Comment: Commenters pointed out that although the proposal is framed as a presumption, the proposed rule, would, in effect, inappropriately establish a per se rule that inpatient admissions that are not expected to last at least 2 midnights are not medically reasonable and necessary (unless the beneficiary is receiving an inpatient-only service or procedure). The commenters stated that the proposed rule offers no legal or medical support for the idea that a 1-day stay that is expected to be a 1-day stay is not medically reasonable and necessary as an inpatient admission. Other commenters requested that CMS clarify that no per se rule would be created that inpatient payment is always inappropriate following procedures not on the inpatient-only list.

Response: The proposed rule did not create a per se standard; rather, consistent with historical instruction, the proposed rule continues the use of a benchmark to ensure a uniform understanding of the circumstances under which an inpatient admission should be ordered or when the care should be provided on an outpatient basis. This common standard is not a per se rule but a necessary reference to ensure similar beneficiary cost-sharing and hospital reimbursement for similar

care. The 2-midnight benchmark, rather, provides that hospital stays expected to last less than 2 midnights are generally inappropriate for inpatient hospital admission and Part A payment absent rare and unusual circumstance to be further detailed in sub-regulatory instruction. In applying this benchmark, we have been clear that this instruction does not override the clinical judgment of the physician to keep the beneficiary at the hospital, to order specific services, or to determine appropriate levels of nursing care or physical locations within the hospital. Rather, this instruction provides a benchmark to ensure that all beneficiaries received consistent application of their Part A benefit to whatever clinical services were medically necessary.

Comment: Commenters urged CMS to consider situations that result in a shorter beneficiary stay than the physician's expectation of care transcending 2 midnights. The commenters stated that in the proposed rule, CMS indicated that it would expect that the majority of such cases to be due to beneficiary death or transfer. Commenters expressed concern that these exceptions are too restrictive and urged CMS to recognize other exceptions, such as when a beneficiary leaves against medical advice (AMA) before reaching the 2-midnight benchmark, when the beneficiary improves more rapidly than expected, or when the beneficiary requires care in the intensive care unit (ICU). One commenter inquired whether a beneficiary who receives intensive services and expires prior to crossing 2 midnights would automatically be classified as appropriately outpatient.

Response: We appreciate industry feedback, and believe the rule, as finalized, provides for sufficient flexibility because of its basis in the physician's expectation of a 2-midnight stay. Such would include situations in which the beneficiary improves more rapidly than the physician's reasonable, documented expectation. Such unexpected improvement may be provided and billed as inpatient care, as the regulation is framed upon a reasonable and supportable expectation, not the actual length of care, in defining when hospital care is appropriate for inpatient payment. We do not believe beneficiaries treated in an intensive care unit should be an exception to this standard, as our 2-midnight benchmark policy is not contingent on the level of care required or the placement of the beneficiary within the hospital. In addition, while we did not specify the situation in which a beneficiary leaves AMA as an exception under the proposed rule, we acknowledge that an AMA departure is usually an unexpected event and that an inpatient admission could still be appropriate provided that the medical record demonstrates a reasonable expectation of a 2-midnight stay when the admission order is written. As we develop our manual guidance to implement this proposed rule, we will identify those unusual situations in which we expect that the 2 midnight benchmark does not apply.

Comment: Commenters voiced concerns that the use of observation would increase under the proposed policy, regardless of CMS' intent to reduce the incidence of long observation stays. Some commenters believed that if the physician would have to predict a greater than 2 midnight stay, only the sickest individuals and those receiving procedures on the inpatient-only list would be admitted as inpatients, while many more beneficiaries would be placed in observation so as to avoid an inaccurate length of stay determination and subsequent short-stay audits. Other commenters believed that because an increase in observation stays will happen, many hospital stays that would generally be appropriate for an inpatient admission under CMS' current 24-hour guidance would now be generally inappropriate for Part A payment unless the 2-midnight benchmark is met. Commenters voiced concern that the increase in observation will lead to a strain in outpatient beds and resources, leading the hospitals to use inpatient beds for beneficiaries in outpatient status who need more intense monitoring than is currently available in outpatient areas without a proportionate increase in outpatient reimbursement from Medicare. Commenters also urged CMS to recalibrate its outpatient payment so that hospitals will be adequately compensated for handling the increase in observation cases, particularly for those stays requiring complex monitoring and intervention. The commenters believed that as beneficiaries have the potential for greater cost-sharing for an observation stay than an inpatient stay, this may lead to greater financial liability for beneficiaries.

Response: While previous guidance provided a 24-hour benchmark to be used in making inpatient admission decisions, we now specify that the 24 hours relevant to inpatient admission decisions are those encapsulated by 2 midnights. As we provide in this final rule, we expect that the decision to admit the beneficiary should be based on the cumulative time spent at the hospital beginning with the initial outpatient service. In other words, if the physician makes the decision to admit after the beneficiary arrived at the hospital and began receiving services, he or she should consider the time already spent receiving those services in estimating the beneficiary's total expected length of stay. For example, if the beneficiary has already passed 1 midnight as an outpatient observation patient or in routine recovery following outpatient surgery, the physician should consider the 2 midnight benchmark met if he or she expects the beneficiary to require an additional midnight in the hospital. This means that the decision to admit becomes easier as the time approaches the second midnight, and beneficiaries in medically necessary hospitalizations should not pass a second midnight prior to the admission order being written. The potential increase in very short (less than 2 midnights) observation stays should be balanced by a significant decrease in long (2 midnights or more) observation stays. Because we expect that this revision should virtually eliminate the use of extended observation, we also anticipate it will concurrently limit beneficiary cost-sharing for outpatient services. We are not expecting any change in the utilization of specific beds or facilities, as the expectation of the duration of needed care is independent of the beneficiary's location at the hospital.

Comment: One commenter inquired about the appropriate use of Condition Code 44 in a situation when the physician expected a stay that met the 2-midnight standard but the beneficiary experienced an unanticipated recovery.

Response: We refer commenters to the instruction provided at section XI.B. of the preamble of this rule, in which we expanded on Condition Code 44 requirements and application. Under this section, we state that providers may continue to change patient status to outpatient during the hospital stay upon meeting the Condition Code 44 requirements. However, we note that Condition Code 44 is not to be used for unexpected events because, as described above, those situations can remain appropriately inpatient. Thus, a beneficiary who experiences an unexpected recovery during a medically necessary stay should not be converted to an outpatient but should remain an inpatient if the 2-midnight expectation was reasonable at the time the inpatient order was written, but unexpectedly the stay did not fully transpire. In contrast, Condition Code 44 is specifically for the situation when the utilization review or management committee determines that the physician has not appropriately

admitted a patient and the physician concurs that the status should be converted to outpatient prior to beneficiary discharge.

Comment: Commenters indicated that inpatient-only procedures that require a 1-day length of stay would be affected by this proposed policy and may not be adequately reimbursed under Medicare Part B. The commenters requested that CMS specify that all services on the inpatient-only list should automatically be deemed to meet inpatient service criteria, even if the beneficiary is in the hospital for less than 2 midnights. Conversely, another commenter suggested that excluding inpatient-only procedures, which may or may not require 2-midnight stays, contradicts a time-based policy.

Response: In the proposed rule, we stated that procedures on the OPPS inpatient-only list are always appropriately inpatient, regardless of the actual time expected at the hospital, so long as the procedure is medically necessary and performed pursuant to a physician order and formal admission. Procedures designated as inpatient-only are deemed statutorily appropriate for inpatient payment at § 419.22(n). As such, we believe that inpatient-only procedures are appropriate for exclusion from the 2-midnight benchmark. Under this final rule, inpatient-only procedures currently performed as inpatient 1-day procedures will continue to be provided as inpatient 1-day procedures, and therefore this rule will not result in any change in status or reimbursement.

Comment: Commenters recommended that CMS remove the 2-midnight guidance for certain procedures, allowing physicians to continue admitting as inpatient high risk, complex beneficiaries who are to undergo a surgery with added complexity, regardless of the expected length of stay. The commenters stated that many Medicare beneficiaries have multiple comorbidities, and the execution of seemingly simple procedures may require more pre-, intra-, and post-operative services than would be necessary for younger or healthier patients, even when there is no expectation that the beneficiary will require a stay of at least 2 midnights. Commenters added that the provision of such services may exceed the level of care typically associated with observation care. Other commenters suggested that CMS explicitly preclude from further review any services that are not typically available in an outpatient setting, such as telemetry.

Response: We agree with commenters that factors such as the procedures being performed and the health status of the beneficiary are important considerations in the decision to keep the beneficiary in the hospital. However, as we note above, the beneficiary's required ''level of care'' is not part of the guidance regarding hospital inpatient admission decisions. Rather, we provide physicians with a 2-midnight admission framework to effectuate appropriate inpatient hospital admission decisions. More specifically, we have stipulated that factors such as the procedures being performed and the beneficiary's condition and comorbidities apply when the physician formulates his or her expectation regarding the need for hospital care, while the decision of whether to admit a beneficiary as an inpatient or keep as an outpatient is based upon the physician's expectation of the beneficiary's required length of stay. In this rule, we have not identified any circumstances where the 2-midnight benchmark restricts the physician to a specific pattern of care, as we have specified that the 2-midnight benchmark, like the previous 24-hour benchmark, does not prevent the physician from providing any service at any hospital regardless of the expected duration of the service. Rather, this policy provides guidance on when the hospitalized beneficiary is appropriate for coverage under Part A benefits as an inpatient, and when the hospitalized beneficiary should receive that treatment as a registered outpatient subject to Part B benefits. On the other hand, we also specify that certain procedures may have intrinsic risks, recovery impacts or complexities that would cause them to be appropriate for inpatient coverage under Part A regardless of the expected length of hospital time a specific physician expects a particular patient to require. We believe that the OPPS Inpatient-Only List identifies those procedures and we have proposed that this is a specific exception to the generally applicable 2 midnight benchmark. We may also specify other potential exceptions to the generally applicable benchmark as we revise our manuals to implement this proposed rule.

Comment: Commenters recommended that the risk of an adverse event as being a determinant in the inpatient admission decision should be removed, qualified as ''high'' or ''unreasonable,'' or narrowly defined to only include risks during the beneficiary's course of treatment that can be addressed or managed by the hospital. The commenters pointed to past trends of inconsistency in the use of risk as a factor in the inpatient admission decision by hospitals and appeal entities. Commenters suggested that, at most, the beneficiary's risk of morbidity or mortality should be a factor considered when making the decision of whether the keep the beneficiary in the hospital or send the beneficiary home, not when determining the appropriate patient status as inpatient or outpatient.

Response: We believe that, due to the nature of the Medicare population, coexisting or concurrent medical conditions are a frequent occurrence. As a result, admission decisions centered around risk must relate to current disease processes or presenting symptoms, and not merely be part of the beneficiary's benign or latent past medical history. We note that ''risk'' in common usage describes an unacceptable probability of an adverse outcome, as in ''risky behavior.'' We reiterate our stance that the decision to hospitalize a beneficiary is a complex medical decision made by the physician in consideration of various risk factors, including the beneficiary's age, disease processes, comorbidities, and the potential impact of sending the beneficiary home. It is up to the physician to make the complex medical decision of whether the beneficiary's risk of morbidity or mortality dictates the need to remain at the hospital because the risk of an adverse event would otherwise be unacceptable under reasonable standards of care, or when the beneficiary may be discharged home. If the resultant length of stay for medically necessary hospitalization is expected to surpass 2 midnights, the physician should admit the patient as an inpatient.

Comment: Commenters pointed out that the complexity of caring for the elderly beneficiary and the limited access to resources in the community continues to be challenging. While a beneficiary may not meet the screening criteria for an inpatient admission, the beneficiary's complex needs and lack of access to medical therapies outside the hospital require the admitting physician to make a judgment as to whether such patients are in greater danger of serious illness or death if they are discharged than if they are admitted, and may result in the hospital being unable to release a beneficiary into the community. Conversely, a commenter wanted to remind CMS that convenience factors or nonmedically necessary care violate the Social Security Act, which excludes custodial care from Medicare coverage.

Response: While we will not dictate the hospital or physician admission decision, we also note that Medicare is statutorily prohibited under section

1862(a)(1)(A) of the Act from paying for services that are not reasonable and necessary. Therefore, we have identified so-called ''social admissions'' and admissions to avoid inconvenience as inappropriate from Medicare payment per the aforementioned statutory exclusion. This is consistent with current manual instructions. We will look for opportunities to offer additional guidance addressing these types of medical necessity decisions as we update our policy manuals.

Comment: Commenters requested that CMS provide clarification for how hospitals receiving beneficiaries from another hospital should make the admission decision under the proposed policy.

Response: We recognize that, in addition to the occurrence of unexpected transfers out of a hospital, there are a number of possible scenarios involving transfers into a hospital that that may impact the length of stay determination under this policy. We noted in the proposed rule that an unexpected transfer out of the sending hospital is one reason why an inpatient stay that lasts less than 2 midnights may still be appropriately inpatient. Due to the complexity of the possible transfer scenarios, we believe that explicit guidance should be reserved for manual instruction. Drafting these instructions will be one of the highest priorities as we develop our implementation instructions.

Comment: Commenters pointed out that, under this proposal, the distinction between inpatient and outpatient may come down to small time discrepancies. For example, a beneficiary whose hospital stay begins shortly before midnight and lasts just over 48 hours will be considered an inpatient because the stay will cross 2 midnights, while a beneficiary whose hospital stay begins shortly after midnight and lasts just under 48 hours will be considered an outpatient because the stay will only cross 1 midnight.

Response: The application of 2 midnights was proposed for the purpose of providing both consistency and clarity. We have expected and continue to expect that physicians will make the decision to keep a beneficiary in the hospital when clinically warranted and will order all appropriate treatments and care in the appropriate location based on the beneficiary's individual medical needs. We also expect that physicians will apply the revised benchmark as they have previously applied the existing benchmark, providing any medically necessary services in an inpatient status whenever the benchmark is met and in all other instances providing identical services to patients staying at the hospital in a day or overnight outpatient status. While we have historically referenced a 24-hour benchmark, we now specify that the 24 hours relevant to inpatient admission decisions are those encapsulated by 2 midnights. This distinction is consistent with our application of Medicare utilization days, which are based on the number of midnights crossed. Medicare charges beneficiaries for utilization days and pays hospitals for utilization days when it applies per diem adjustments, such as the transfer adjustment. A beneficiary who is admitted just before midnight and discharged 36 hours later is currently charged 2 utilization days, while a beneficiary admitted just after midnight is charged 1 day. In addition, the use of 2 midnights is an easy concept for beneficiaries to understand in assessing the appropriateness of their assigned status, associated coverage, and impacts.

Comment: Commenters provided alternate proposals for guiding inpatient admissions and medical review. Some commenters suggested that physicians are not apprised of admission criteria, but rather the medical treatment necessary for the beneficiary, and suggested that case management be permitted to make inpatient admission determinations, which could be concurred or nonconcurred to by the treating physician. Conversely, other commenters believed the physician was most apprised of the patient condition and, therefore, the need for inpatient admission or care spanning 2 midnights. As such, some commenters believed the physician order should trigger a presumption of appropriate payment for medical review purposes. One commenter suggested good faith protections for facilities in strict adherence to their hospital comprised utilization review plan. Another commenter disagreed with the need for any change to the current medical review policy.

Response: In the proposed rule, we focused on clarifying and modifying the distinction between hospitalization as an outpatient and hospitalization as an inpatient. While the proposed approach arose out of significant consideration for provider impact, ease in implementation and operationalization, we will assess commenter feedback falling within the scope of CMS' policy in implementing changes to our manual provisions.

Comment: Commenters requested further guidance to clarify what criteria support a reasonable and necessary inpatient admission. The commenters' suggested sources of such guidance included evidence-based guidelines offered through the Agency for Healthcare Research and Quality (AHRQ) National Guidelines Clearinghouse and the various medical specialty societies and commercial hospital screening guidelines. Some commenters also suggested that inpatient admissions be deemed reasonable and necessary based on the use of such sources. Another commenter indicated that a time-based policy contradicts CMS instructions contained in the Program Integrity Manual pertaining to the use of screening tools as part of the review of inpatient hospital claims. Regardless of the criteria chosen, commenters iterated that CMS and its contractors must update existing inpatient admission guidance and policies to ensure consistency in application by all Medicare review contractors. Commenters also inquired whether providers would have the opportunity to comment on any additional guidance that will be created to implement this rule.

Response: Medicare review contractors must abide by CMS policies in conducting payment determinations, but are permitted to take into account evidence-based guidelines or commercial utilization tools that may aid such a decision. We also acknowledge that this type of information may be appropriately considered by the physician as part of the complex medical judgment that guides his or her decision to keep a beneficiary in the hospital and formulation of the expected length of stay. As we update our manuals and take additional steps to implement this rule, we anticipate using our usual processes to develop and release subregulatory guidance such as manual instructions and educational materials, which may include open door forums, regional meetings, correspondence and other ongoing interactions with stakeholders; and that our contractors will continue to involve local entities as they implement these rules.

Comment: Several commenters indicated that CMS should delay enforcement of the revised admissions criteria until a time after October 1, 2013, due to the significant system changes and educational efforts that will be required. Some commenters indicated that CMS should use this delay in order to conduct further research and collaborate with providers, while others suggested that CMS conduct a thorough analysis of current payment policy and planned payment reforms that could affect inpatient admission decisions, including those

with implications for patient safety, quality, and beneficiary cost-sharing, before finalizing its guidance. Other commenters suggested that claim reviews for inpatient stays of greater than 2 midnights should continue without evidence of gaming for a period of time following implementation of the new policy to ensure that hospitals are properly billing under the revised criteria. The commenters stated that after that time has passed, reviews of inpatient stays longer than 2 midnights would be based on evidence of overutilization.

Response: We proposed only a change in the inpatient admissions benchmark from an hourly expectation (24 hours) to a daily (2-midnights) expectation. We do not believe that delays in implementation are necessary or desirable, and we expect, through collaboration with stakeholders, to develop additional guidance and instruction as part of that implementation.

Comment: Commenters questioned the applicability of the proposed rule to differing types of hospital facilities. Commenters specifically requested clarity regarding application of the rule to IRFs and IPFs. Commenters further asserted that this distinction may conflict with State laws requiring inpatient admissions post 24 hours, and such States should be granted exception.

Response: In the proposed rule, our reference to section 1861(e) of the Act was intended to specify that CAHs were included in the proposed policies, not that we were proposing that IPFs or other non-IPPS hospitals should be excluded. Having considered the public comments to the proposed rule, we believe that all hospitals, LTCHs, and CAHs, with the exception of IRFs, would appropriately be included in our final policies regarding the 2-midnight admission guidance and medical review criteria for determining the general appropriateness of inpatient admission and Part A payment. Due to the inherent differences in the operation of and beneficiary admissions to IRFs, such providers must be excluded from the aforementioned admission guidelines and medical review instruction. We disagree with the commenters' assertion that the 2-midnight admission and medical review policies conflict with existing state laws regarding observation. The 2-midnight benchmark does not prohibit physicians from ordering inpatient admission in accordance with state law; rather, this policy indicates when Medicare payment will be deemed appropriate. To the extent that State law requires admission in situations where Medicare payment would not be appropriate, providers should work with their States to resolve those discrepancies.

Comment: Commenters indicated that the proposed policy, which clarifies when a beneficiary becomes an inpatient, promotes the integrity and accuracy of the 340B program. They stated that the 340B program creates an incentive for hospitals to keep beneficiaries in observation status for the purpose of obtaining the deeply discounted 340B acquisition price that would otherwise by unavailable. Thus, they added, the 340B spread creates a financial incentive for 340B hospitals to keep beneficiaries in outpatient/observation status for the sole purpose of administering drugs.

Response: We appreciate the observation of the commenters and concur that this policy promotes consistent application of an inpatient status to all stakeholders.

(3) Medical Review of Inpatient Hospital Admissions Under Part A

Under this revised policy, services designated by the OPPS Inpatient-Only list as inpatient-only, would continue to be appropriate for inpatient hospital admission and payment under Medicare Part A. In addition, surgical procedures, diagnostic tests, and other treatments would be generally deemed appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation. We proposed, and are now finalizing, two distinct, though related, medical review policies, a 2-midnight *presumption* and a 2-midnight *benchmark.* Under the 2-midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order will be presumed generally appropriate for Part A payment and will not be the focus of medical review efforts absent evidence of systematic gaming, abuse or delays in the provision of care in an attempt to qualify for the 2-midnight presumption (that is, inpatient hospital admissions where medically necessary treatment was not provided on a continuous basis throughout the hospital stay and the services could have been furnished in a shorter timeframe). Beneficiaries should not be held in the hospital absent medically necessary care for the purpose of meeting the 2-midnight benchmark. Review contractors will also continue to assess claims in which the beneficiary span of care after admission crosses 2 midnights:

- To ensure the services provided were medically necessary;
- To ensure that the stay at the hospital was medically necessary;
- To validate provider coding and documentation as reflective of the medical evidence;
- When the CERT Contractor is directed to do so under the Improper Payments Elimination and Recovery Improvement Act of 2012 (Pub. L. 112–248); or
- If directed by CMS or other authoritative governmental entity (including but not limited to the HHS Office of Inspector General and Government Accountability Office).

Conversely, under this revised policy, CMS' medical review efforts will focus on inpatient hospital admissions with lengths of stay crossing only 1 midnight or less after admission (that is, only 1 Medicare utilization day, as defined in 42 CFR 409.61 and implemented in the MBPM, Chapter 3, Section 20.1). As previously described, such claims have traditionally demonstrated the largest proportion of inpatient hospital improper payments under Medicare Part A. If the physician admits the beneficiary as an inpatient but the beneficiary is in the hospital for less than 2 midnights after the order is written, CMS and its medical review contractors will not presume that the inpatient hospital status was reasonable and necessary for payment purposes, but may instead evaluate the claim pursuant to the 2-midnight benchmark. Medicare review contractors will (a) evaluate the physician order for inpatient admission to the hospital, along with the other required elements of the physician certification, (b) the medical documentation supporting the expectation that care would span at least 2 midnights, and (c) the medical documentation supporting a decision that it was reasonable and necessary to keep the patient at the hospital to receive such care, in order to determine whether payment under Part A is appropriate.

In their review of the medical record, Medicare review contractors will consider complex medical factors that support a reasonable expectation of the needed duration of the stay relative to the 2-midnight benchmark. Both the decision to keep the beneficiary at the hospital and the expectation of needed duration of the stay are based on such complex medical factors as beneficiary medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk (probability) of an adverse event occurring during the

time period for which hospitalization is considered. In other words, if it was reasonable for the physician to expect the beneficiary to require a stay lasting 2 midnights, and that expectation is documented in the medical record, inpatient admission is generally appropriate, and payment may be made under Medicare Part A; this is regardless of whether the anticipated length of stay did not transpire due to unforeseen circumstances such as beneficiary death or transfer (so long as the physician's order and certification requirements also are met). As discussed above, an inpatient admission is appropriate and Part A payment may also be made in the case of services on Medicare's inpatient-only list, regardless of the expected length of stay.

Comment: Some commenters shared concerns regarding the proposed method of calculating the length of stay for purposes of the 2-midnight benchmark, beginning when the beneficiary is moved from any outpatient area to a bed in the hospital in which the additional hospital services will be provided. Commenters noted that hospital capacity issues can lead to situations in which a beneficiary is boarded in the emergency department until a bed becomes available, which can be hours after the admission order is written. In other instances, the commenters added, an inpatient admission may be planned after a surgical procedure and the beneficiary becomes an inpatient when he or she reports to the operating room for preoperative assessment and preparation. Commenters pointed out that if the clock does not start until beneficiary movement to another area of the hospital occurs, the beneficiary may not meet the 2-midnight benchmark although he or she was receiving treatment in the hospital for greater than 2 midnights. Commenters provided various alternate suggestions for when the clock should start. Many commenters suggested that CMS start the clock the earliest of: (1) When the physician writes an order for admission or observation; (2) when the beneficiary is treated in the emergency department; or (3) when the beneficiary is placed in a bed for observation. Other commenters suggested that the clock should begin when the beneficiary meets inpatient admission criteria or when the nursing intake notes specify the time the beneficiary is admitted to the floor and is put in a bed. Regardless of the decision CMS made on this point, commenters requested that clarification be provided on when the inpatient order should be written and how the time should be counted for medical review purposes.

Response: We agree with the concerns noted by commenters, and are revising the proposed rule accordingly. In this final rule, we specify that the ordering physician may consider time the beneficiary spent receiving outpatient services (including observation services, treatments in the emergency department, and procedures provided in the operating room or other treatment area) for purposes of determining whether the 2-midnight benchmark is expected to be met and therefore inpatient admission is generally appropriate. For beneficiaries who do not arrive through the emergency department or are directly receiving inpatient services (for example, inpatient admission order written prior to admission for an elective admission or transfer from another hospital), the starting point for medical review purposes will be from the time the patient starts receiving any services after arrival at the hospital. We emphasize that the time the beneficiary spent as an outpatient before the inpatient admission order is written will not be considered inpatient time, but may be considered by physicians in determining whether a patient should be admitted as an inpatient, and during the medical review process for the limited purpose of determining whether the 2-midnight benchmark was met and therefore payment is generally appropriate under Part A. Claims in which a medically necessary inpatient stay spans at least 2 midnights after the beneficiary is formally admitted as an inpatient will be presumed appropriate for inpatient admission and inpatient hospital payment and will generally not be subject to medical review of the inpatient admission, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-midnight presumption.

Comment: Commenters requested clarification regarding the distinction between inpatient time and outpatient time for purposes of meeting the 2-midnight benchmark, specifically for those beneficiaries who are first treated in observation status and then later as hospital inpatients pursuant to a physician's order. Commenters recommended that CMS consider observation care to count toward the 2-midnight rule when complications arise that lead to previously unanticipated extended care in accord with requirements for skilled nursing facility eligibility.

Response: As noted above, we will allow the physician to consider time spent in the hospital as an outpatient in making their inpatient admission decision. This is consistent with CMS existing instructions and medical review guidance, which allow physicians and Medicare review contractors to account for the beneficiary's medical history and physical condition prior to the inpatient admission decision. Therefore, if upon beneficiary presentation, the physician is unable to make an evaluation and corresponding expected length of stay determination, the physician may first monitor the beneficiary in observation or continue to perform diagnostics in the outpatient arena. If the beneficiary's medical needs and condition after 1 midnight in outpatient status dictate the need for an additional midnight within the hospital receiving medically necessary care, the physician may consider the care in the outpatient setting when making his or her admission decision. Medicare review contractors would similarly apply the 2-midnight benchmark to all time spent within the hospital receiving medically necessary services in their claim evaluation.

We reiterate that the physician order, the remaining elements of the physician certification, and formal inpatient admission remain the mandated means of inpatient admission. While outpatient time may be accounted for in application of the 2-midnight benchmark, it may not be retroactively included as inpatient care for skilled nursing care eligibility or other benefit purposes. Inpatient status begins with the admission based on a physician order.

Comment: Commenters expressed concern about the additional scrutiny that 1-day inpatient hospital stays would undergo under this policy. Commenters also were particularly interested in how the review contractors would review inpatient stays that lasted less than 2 midnights, including whether current review criteria would continue to be utilized for such reviews. The commenters requested that CMS define situations in which a hospital stay lasting less than 2 midnights would properly qualify as inpatient.

Response: If the physician admits the beneficiary as an inpatient but the beneficiary is in the hospital for less than 2 midnights after the admission begins, CMS and the Medicare review contractors will not presume that the inpatient hospital admission was reasonable and necessary for payment purposes, but will apply the 2-midnight benchmark in conducting medical review. In making their determination of whether the inpatient admission is appropriate, Medicare review

contractors will evaluate: (a) The physician order for inpatient admission to the hospital, along with the other required elements of the physician certification; (b) the medical documentation supporting that the order was based on an expectation of need for care spanning at least 2 midnights; and (c) the medical documentation supporting a decision that it was reasonable and necessary to keep the patient at the hospital to receive such care. In their review of the medical record, Medicare review contractors will consider complex medical factors that support a reasonable expectation of the needed duration of the stay relative to the 2-midnight benchmark. These include such factors as beneficiary medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event.

Comment: Commenters asserted that the proposed rule penalizes efficiency, as those hospitals that are able to treat beneficiaries in less than 2 midnights will be able to admit fewer beneficiaries than those less efficient hospitals who do not have the same resources. Other commenters expressed concern that the new proposed policy would encourage hospitals to hold beneficiaries in the hospital solely for the purpose of meeting the 2-midnight presumption and avoid audits of their claims. The commenters stated that consequences of such practices on the beneficiaries could include prolonged exposure to additional medical risks and would also lead to increased costs to the Medicare program, due to medically unnecessary time in the hospital. Conversely, some commenters indicated that they did not believe that hospitals would not hold patients for longer than necessary to meet inpatient requirements.

Response: We have noted that the decision to admit is based on an expectation of medically necessary care transcending 2 midnights resulting from the practitioner's consideration of the beneficiary's condition and medical needs. We will monitor all hospitals for intentional or unwarranted delays in the provision of care, which may result in increased inpatient admissions secondary to the 2 midnight instruction. We are also cognizant of concerns related to unnecessarily elongated hospital admissions, and will be monitoring for such patterns of systemic delays indicative of fraud or abuse. If a hospital is unnecessarily holding beneficiaries to qualify for the 2-midnight presumption, CMS and/or its contractors may conduct review on any of its inpatient claims, including those which surpassed 2 midnights after admission.

Comment: One commenter stated that while it is reasonable that a medically necessary hospital stay crossing 2 midnights may be appropriately billed as inpatient, there should be no presumption that such a 2-midnight stay was itself medically necessary simply because a patient was in the hospital 2 consecutive nights. The commenter stated that the proposed rule includes a requirement that review will only be permitted when the error rate is sufficient to warrant auditing activity; however, the audit that would establish this error would itself be precluded under CMS' presumption. The commenter stated that, alternatively, data analysis of the claims should remain the foundation for selection of claims for medical record review to determine whether the documentation supports the claim as billed. The commenter believed that a presumption of medical necessity based on the time a beneficiary stays in the hospital places the Medicare trust fund and taxpayers at risk.

Response: We note that it was not our intent to suggest that a 2-midnight stay was presumptive evidence that the stay at the hospital was necessary; rather, only that if the stay was necessary, it was appropriately provided as an inpatient stay. We have discussed in response to other comments that, in accordance with our statutory obligations, some medical review is always necessary to ensure that services provided are reasonable and necessary, and that we will continue to review these longer stays for the purposes of monitoring, determining correct coding, and evaluating the medical necessity for the beneficiary to remain at the hospital, irrespective of the inpatient or outpatient ''status'' to which the beneficiary was assigned. In addition, claims that evidence that a hospital is effectuating systematic abuse of the 2-midnight presumption, such as unexplained delays in the provision of care or aberrancies in billing, may be subject to medical review despite surpassing 2 midnights after admission.

Comment: Commenters requested that CMS provide guidance on what would constitute ''abuse'' or ''gaming'' for this review purpose. Some commenters were concerned that enabling Medicare review contractors to make these determinations would unravel the presumption if the contractors had incentives to identify erroneous claims. Other commenters believed that Medicare contractors, who have expertise in utilization review and Medicare data, should be tasked with identifying providers that are gaming or abusing the system for purposes of meeting the 2-midnight presumption. Comments also suggested that CMS examine hospitals' utilization review process rather than rely on claim outputs. Commenters also urged CMS to be clear that audits will occur only if a pattern is detected.

Response: In the proposed rule, we stated that patient status reviews for inpatient admissions with lengths of stay greater than 2 midnights after admission would typically be conducted if we suspect that a provider is using the 2-midnight presumption to effectuate systematic abuse or gaming. We have elaborated on our review plans above and summarize by stating that while we have a statutory obligation to ensure that all services are medically necessary and correctly paid, we believe that these changes in our benchmarks and the additional guidance accompanying them will allow us to reduce the administrative burden of reviews. We will do this by reviewing stays spanning at least 2 midnights after admission for the purpose of monitoring and responding to patterns of incorrect DRG assignments, inappropriate or systemic delays, and lack of medical necessity for the stay at the hospital, but not for the purpose of routinely denying payment for such inpatient admissions on the basis that the services should have been provided on an outpatient basis. We expect to shift our attention to the smaller anticipated volume of 0 and 1 day short stays and then, to the extent that facilities correctly apply the proposed benchmark, away from short stays to other areas with persistently high improper payment rates.

Comment: Commenters voiced concerns that while CMS proposed that those inpatient hospital admissions meeting the 2-midnight benchmark would be generally appropriate for Part A payment, there is no guarantee that the Medicare contractors would follow this guidance. Some commenters expressed apprehension that the time-based policy would not result in fewer reviews, as the policy stated that contractors could review whether the physician's expectation was reasonable, while others thought the doors would be opened to more hospital claim audits focusing on the need for the beneficiary to stay in the hospital for greater than 2 midnights. Commenters also sought assurance from CMS that reviews would be conducted based on the information the physician had available at the time he or she developed the expectation of a 2-midnight stay and wrote the order pursuant to that expectation.

Response: We acknowledge that it is very important that clear and consistent instructions are provided to facilities, physicians, and Medicare review contractors. We intend to quickly develop implementation instructions, manual guidance, and additional education to ensure that all entities receive initial and ongoing guidance in order to promote consistent application of these changes and repeatable and reproducible decisions on individual cases. We intend to ensure that our instructions to providers and reviewers alike emphasize that the decision to admit should be based on and evaluated in respect to the information available to the admitting practitioner at the time of the admission.

After consideration of the public comments we received, we are including in this final rule several revisions and clarifications to the proposed policy. First, we are finalizing at § 412.3(e)(1) the 2-midnight benchmark as proposed at § 412.3(c)(1), that services designated by the OPPS Inpatient-Only list as inpatient-only would continue to be appropriate for inpatient hospital admission and payment under Medicare Part A. In addition, surgical procedures, diagnostic tests, and other treatments would be generally deemed appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation. We proposed at § 412.3(c)(2), and are finalizing at § 412.3(e)(2), that if an unforeseen circumstance, such as beneficiary death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least 2 midnights, the patient may still be considered to be appropriately treated on an inpatient basis, and the hospital inpatient payment may be made under Medicare Part A. We proposed, and are now finalizing, two distinct, although related, medical review policies, a 2-midnight *benchmark* and a 2-midnight *presumption.* The 2-midnight benchmark represents guidance to admitting practitioners and reviewers to identify when an inpatient admission is generally appropriate for Medicare coverage and payment, while the 2-midnight presumption directs medical reviewers to select claims for review under a presumption that the occurrence of 2 midnights after admission appropriately signifies an inpatient status for a medically necessary claim. The starting point for the 2-midnight benchmark will be when the beneficiary begins receiving hospital care on either an inpatient basis or outpatient basis. That is, for purposes of determining whether the 2-midnight benchmark will be met and, therefore, whether inpatient admission is generally appropriate, the physician ordering the admission should account for time the beneficiary spent receiving outpatient services such as observation services, treatments in the emergency department, and procedures provided in the operating room or other treatment area. From the medical review perspective, while the time the beneficiary spent as an outpatient before the admission order is written will not be considered inpatient time, it may be considered during the medical review process for purposes of determining whether the 2-midnight benchmark was met and, therefore, whether payment is generally appropriate under Part A. For beneficiaries who do not arrive through the emergency department or are directly receiving inpatient services (for example, inpatient admission order written prior to admission for an elective admission or transfer from another hospital), the starting point for medical review purposes will be when the beneficiary starts receiving services following arrival at the hospital. We proposed that both the decision to keep the patient at the hospital and the expectation of needed duration of the stay would be based on such factors as beneficiary medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. In this final rule, we now are clarifying that risk (or probability) of an adverse event relates to occurrences during the time period for which hospitalization is considered.

We are finalizing that inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order will be presumed generally appropriate for Part A payment and will not be the focus of medical review efforts absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-midnight presumption. We also are clarifying in this final rule how we will instruct contractors to review inpatient stays spanning less than 2 midnights after admission. Such claims would not be subject to the presumption that services were appropriately provided during an inpatient stay rather than an outpatient stay because the total inpatient time did not exceed 2 midnights. However, upon medical review, the time spent as an outpatient will be counted toward meeting the 2-midnight benchmark that the physician is expected to apply to determine the appropriateness of the decision to admit. In other words, even though the inpatient admission was for only 1 Medicare utilization day, medical reviewers will consider the fact that the beneficiary was in the hospital for greater than 2 midnights following the onset of care when making the determination of whether the inpatient stay was reasonable and necessary. For those admissions in which the basis for the physician expectation of care surpassing 2 midnights is reasonable and well-documented, reviewers may apply the 2-midnight benchmark to incorporate all time receiving care in the hospital. We will continue to use our existing monitoring and audit authority, such as the CERT program, to ensure that our review efforts focus on those subsets of claims with the highest error rates and reduce the administrative burden for those subsets that have demonstrated compliance with our clarified and modified guidance.

4. Impacts of Changes in Admission and Medical Review Criteria

In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27649 through 27650), we discussed our actuaries' estimate that our proposed 2-midnight policy (referred to in this final rule as the 2-midnight benchmark and the 2-midnight presumption) would increase IPPS expenditures by approximately $220 million. These additional expenditures result from an expected net increase in hospital inpatient encounters due to some encounters spanning more than 2 midnights moving to the IPPS from the OPPS, and some encounters of less than 2 midnights moving from the IPPS to the OPPS. Specifically, our actuaries examined FY 2009 through FY 2011 Medicare claims data for extended hospital outpatient encounters and shorter stay hospital inpatient encounters and estimated that approximately 400,000 encounters would shift from outpatient to inpatient and approximately 360,000 encounters would shift from inpatient to outpatient, causing a net shift of 40,000 encounters. These estimated shifts of 400,000 encounters from outpatient to inpatient and 360,000 encounters from inpatient to outpatient represent a significant portion of the approximately 11 million encounters paid under the IPPS. The net shift of 40,000 encounters represents an increase of approximately 1.2 percent in the number of shorter stay hospital inpatient encounters paid under the IPPS. Because shorter stay hospital inpatient encounters currently represent approximately 17 percent of the IPPS expenditures, our actuaries estimated

that 17 percent of IPPS expenditures would increase by 1.2 percent under our proposed policy. These additional expenditures are partially offset by reduced expenditures from the shift of shorter stay hospital inpatient encounters to hospital outpatient encounters. Our actuaries estimated that, on average, the per encounter payments for these hospital outpatient encounters would be approximately 30 percent of the per encounter payments for the hospital inpatient encounters. In light of the widespread impact of the proposed 2-midnight policy on the IPPS and the systemic nature of the issue of inpatient status and improper payments under Medicare Part A for short-stay inpatient hospital claims, we stated our belief that it is appropriate to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to propose to offset the estimated $220 million in additional IPPS expenditures associated with the proposed policy. This special exceptions and adjustment authority authorizes us to provide ''for such other exceptions and adjustments to [IPPS] payment amounts . . . as the Secretary deems appropriate.'' We proposed to reduce the standardized amount, the hospital-specific rates, and the Puerto Rico-specific standardized amount by 0.2 percent.

Comment: Commenters generally did not support the proposed -0.2 percent payment adjustment. Comments included the following assertions: CMS actuaries' estimated increase in IPPS expenditures of $220 million was unsupported and insufficiently explained to allow for meaningful comment; CMS did not provide sufficient rationale for the use of our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act; CMS should not be adjusting the IPPS payment rates for expected shifts in utilization between inpatient and outpatient; CMS did not take into account the impact of the Part B Inpatient Billing proposed rule in developing its estimates; CMS should provide parallel treatment regarding the financial impact of both the medical review policy in the FY 2014 IPPS/LTCH PPS proposed rule and the policies in the Part B Inpatient Billing proposed rule and offset and restore the $4.8 billion dollar reduction to hospital payments over 5 years contained in the Part B Inpatient Billing proposed rule; and CMS' proposed policy was a coverage decision and CMS should not adjust IPPS rates for coverage decisions.

Response: We disagree with commenters who indicated that our actuaries' estimated increase in IPPS expenditures of $220 million was unsupported and insufficiently explained to allow for meaningful comment. In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27649), we specifically discussed the methodology used and the components of the estimate. Our actuaries examined FY 2009 to FY 2011 claims data. Based on this examination, we stated the number of encounters our actuaries estimated would shift from inpatient to outpatient (360,000) and the number of encounters they estimated would shift from outpatient to inpatient (400,000). We described the methodology we used to translate this net shift of 40,000 encounters into our $220 million estimate, including an estimate of the increase these 40,000 encounters represent in shorter stay hospital inpatient encounters (1.2 percent), the share that expenditures for shorter stay hospital inpatient encounters represent of IPPS expenditures (17 percent), and our estimate of the payment difference between OPPS and IPPS for these encounters (OPPS payment for these encounters was estimated to be 30 percent of the IPPS payment for these encounters). In addition to the opportunity to comment on the estimate, any component of the estimate, or the methodology, commenters had an opportunity to provide alternative estimates for us to consider.

In determining the estimate of the number of encounters that would shift from outpatient to inpatient, our actuaries examined outpatient claims for observation or a major procedure. Claims not containing observation or a major procedure were excluded. The number of claims spanning 2 or more midnights based on the dates of service that were expected to become inpatient was approximately 400,000. This estimate did not include any assumption about outpatient encounters shorter than 2 midnights potentially becoming inpatient encounters.

In determining the estimate of the number of encounters that would shift from inpatient to outpatient, our actuaries examined inpatient claims containing a surgical MS–DRG. Claims containing medical MS–DRGs were excluded. The number of claims spanning less than 2 midnights based on the length of stay that were expected to become outpatient, after excluding encounters that resulted in death or transfers, was approximately 360,000.

The estimates of the shifts in encounters as described above were primarily based on FY 2011 Medicare inpatient and outpatient claims data. However, our actuaries also examined FY 2009 and FY 2010 Medicare inpatient and outpatient claims data and found the results for the earlier years were consistent with the FY 2011 results.

While there is a certain degree of uncertainty surrounding any cost estimate, our actuaries have determined that the methodology, data, and assumptions used are reasonable for the purpose of estimating the overall impact of our proposed policy. We note that the assumptions used for purposes of reasonably estimating the overall impact in FY 2014 should not be construed as absolute statements about every individual encounter. For example, we fully expect that not every single surgical MS–DRG encounter spanning less than 2 midnights will shift to outpatient and that not every single outpatient observation stay or major surgical encounter spanning more than 2 midnights will shift to inpatient.

We also disagree with commenters who indicated that we did not provide sufficient rationale for the use of our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act. We discussed that the issue of patient status has a substantial impact on improper payments under Medicare Part A for short-stay inpatient hospital claims, citing the fact that the majority of improper payments under Medicare Part A for short-stay inpatient hospital claims have been due to inappropriate patient status. In 2012, for example, the CERT contractor found that inpatient hospital admissions for 1-day stays or less had a Part A improper payment rate of 36.1 percent. The improper payment rate decreased significantly for 2-day or 3-day stays, which had improper payment rates of 13.2 percent and 13.1 percent, respectively. We stated that we believed the magnitude of these national figures demonstrates that issues surrounding the appropriate determination of a beneficiary's patient status are not isolated to a few hospitals. We also noted that the RAs had recovered more than $1.6 billion in improper payments because of inappropriate beneficiary patient status. While we agree with commenters that our exceptions and adjustments authority should not be routinely used in the IPPS system, we believe that the systemic and widespread nature of this issue justifies an overall adjustment to the IPPS rates and such an adjustment is authorized under section 1886(d)(5)(I)(i) of the Act.

For similar reasons, while we generally agree with commenters that it is not necessary to routinely estimate utilization shifts to ensure appropriate IPPS payments, this is a unique situation. Policy clarifications such as

this do not usually result in utilization shifts of sufficient magnitude and breadth to significantly impact the IPPS. In this situation, we believe it would be inappropriate to ignore such a utilization shift in the development of the IPPS payment rates.

With respect to the comments that we did not take into account the impact of the Part B Inpatient Billing proposed rule in developing our estimates, we note that our actuaries did take those impacts into account in developing our proposed adjustment. Our estimate of the net shift in FY 2014 encounters between inpatient and outpatient would have been substantially higher in the absence of the policies discussed in the Part B Inpatient Billing proposed rule, in particular the discussion of timely filing. Specifically, in the absence of the timely filing requirement, there would be fewer inpatient encounters estimated to become outpatient encounters, which would have resulted in a larger cost than our estimated $220 million.

With respect to the comment that CMS should provide parallel treatment regarding the financial impact of the medical review policy in the FY 2014 IPPS/LTCH PPS proposed rule and the interrelated Part B Inpatient Billing proposed rule by offsetting and restoring the estimated $4.8 billion dollar reduction to hospital payments contained in that rule, we note that, although we estimated a decrease in expenditures as a result of our proposed Part B inpatient billing policy, this decrease in expenditures is offset by the costs of the significant number of related administrative appeal decisions as well as CMS Ruling 1455–R, which allows hospitals to seek payment of Part B inpatient services on claims filed outside the timely filing period. As discussed in greater detail in the Regulatory Impact Analysis in the Part B Inpatient Billing proposed rule (78 FR 16643), the combined impact of the appeals decisions, CMS Ruling 1455–R, and Part B inpatient billing policy, to which the 12-month timely filing requirement applies, is an estimated cost to the Medicare program of $1.03 billion over the CY 2013 to CY 2017 time period. We estimate in the Regulatory Impact Analysis of the final Part B inpatient payment policy in this final rule that the combined impact of the appeals decisions, CMS Ruling 1455–R, and the Part B inpatient billing policy will cost the Medicare program $1.260 billion over the CY 2013 to CY 2017 time period.

Finally, we disagree with those comments asserting that the modification and clarification of our current instructions regarding the circumstances under which Medicare will generally pay for a hospital inpatient admission in order to improve hospitals' ability to make appropriate admission decisions are actually coverage decisions in the context of this adjustment. As we clearly stated in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27648), we will continue to review individual claims to ensure the hospital services furnished to beneficiaries are ''reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,'' as required by section 1862(a)(1) of the Act. Any hospital service determined to be not reasonable or necessary may not be paid under Medicare Part A or Part B. In the context of this adjustment, these are not new hospital services.

Our actuaries continue to estimate there will be approximately $220 million in additional expenditures resulting from our 2-midnight benchmark and 2-midnight presumption medical review policies. This net increase in hospital inpatient encounters is due to some encounters spanning more than 2 midnights moving to the IPPS from the OPPS, and some encounters of less than 2 midnights moving from the IPPS to the OPPS. Therefore, after consideration of the comments we received, and for the reasons described above, we are finalizing a reduction to the standardized amount, the hospital-specific rates, and the Puerto Rico-specific standardized amount of −0.2 percent to offset the additional $220 million in expenditures.

XII. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2013 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the policies set forth in this final rule. MedPAC recommendations for the IPPS for FY 2014 are addressed in Appendix B to this final rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's Web site at: *http://www.medpac.gov*.

XIII. Other Required Information

A. Requests for Data From the Public

In order to respond promptly to public requests for data related to the prospective payment system, we have established a process under which commenters can gain access to raw data on an expedited basis. Generally, the data are now available on compact disc (CD) format. However, many of the files are available on the Internet at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. We listed the data files and the cost for each file, if applicable, in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27746 through 27748).

Commenters interested in discussing any data used in constructing the proposed rule or this final rule should contact should contact Nisha Bhat at (410) 786–5320.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

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.

In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27748 through 27755), we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs). We discuss and respond to any public comments we received in the relevant sections.

2. ICRs for Add-On Payments for New Services and Technologies

Section II.I.1. of the preamble of the proposed rule and this final rule discusses add-on payments for new