ATSDR support for and collaboration with tribes, and to improve the health of tribes by pursuing goals that include assisting in eliminating the health disparities faced by Indian Tribes; ensuring that access to critical health and human services and public health services is maximized to advance or enhance the social, physical, and economic status of American Indian/Alaska Native (AI/AN) people; and promoting health equity for all AI/AN people and communities. To advance these goals, CDC/ATSDR conducts government-to-government consultations with elected tribal officials or their authorized representatives. Consultation is an enhanced form of communication that emphasizes trust, respect, and shared responsibility. It is an open and free exchange of information and opinion among parties that leads to mutual understanding and comprehension.

Matters for Discussion: The TAC and CDC leaders' discussions will include the following public health topics: Adverse childhood experiences, e-cigarettes, motor vehicle-related injury prevention, and CDC's budget.

During the 14th Biannual Tribal Consultation Session, tribes and CDC leaders will engage in a listening session with CDC's director and roundtable discussions with CDC senior leaders. Tribes will also have an opportunity to present testimony about tribal health issues.

Tribal leaders are encouraged to submit written testimony by January 8, 2016, to Alleen R. Weathers, Public Health Advisor for the Tribal Support Unit, OSTLTS, via mail to 4770 Buford Highway NE., MS E–70, Atlanta, Georgia, 30341–3717, or email *TribalSupport@cdc.gov.*

Based on the number of tribal leaders giving testimony and the time available, it may be necessary to limit the time for each presenter.

The agenda is subject to change as priorities dictate.

Information about the TAC, CDC/ATSDR's Tribal Consultation Policy, and previous meetings can be found at the following Web link: *http://www.cdc.gov/tribal.*

Contact person for more information: Alleen R. Weathers, Public Health Advisor, CDC/OSTLTS, 4770 Buford Highway NE., MS E–70, Atlanta, Georgia 30341–3717; email: *alleen.weathers@cdc.hhs.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015–30357 Filed 11–30–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1658–NC]

RIN 0938–ZB23

Medicare Program; Inpatient Prospective Payment Systems; 0.2 Percent Reduction

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

ACTION: Notice with comment period.

SUMMARY: In accordance with the Court's October 6, 2015 order in *Shands Jacksonville Medical Center, Inc., et al.* v. *Burwell, No. 14–263* (D.D.C.) and consolidated cases that challenge the 0.2 percent reduction in inpatient prospective payment systems (IPPS) rates to account for the estimated $220 million in additional FY 2014 expenditures resulting from the 2-midnight policy, this notice discusses the basis for the 0.2 percent reduction and its underlying assumptions and invites comments on the same in order to facilitate our further consideration of the FY 2014 reduction. We will consider and respond to the comments received in response to this notice, and to comments already received on this issue in a final notice to be published by March 18, 2016.

DATES: *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. e.s.t. on February 2, 2016.

ADDRESSES: In commenting, refer to file code CMS–1658–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1658–NC, P.O. Box 8013, Baltimore, MD 21244–8013.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1658–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

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

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

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

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT: Ing-Jye Cheng, (410) 786–2260 or Don Thompson, 410–786–6504.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have

been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

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

I. Background

In the final rule titled ''Medicare Program; Hospital Inpatient Prospective Payment Systems for the Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Final Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status'' (hereinafter referred to as the FY 2014 IPPS/LTCH PPS final rule), we adopted the 2-midnight policy effective October 1, 2013 (78 FR 50906 through 50954). Under the 2-midnight policy, an inpatient admission is generally appropriate for Medicare Part A payment if the physician (or other qualified practitioner) admits the patient as an inpatient based upon the expectation that the patient will need hospital care that crosses at least 2 midnights. In assessing the expected duration of necessary care, the physician (or other practitioner) may take into account outpatient hospital care received prior to inpatient admission. If the patient is expected to need less than 2 midnights of care in the hospital, the services furnished should generally be billed as outpatient services. Our actuaries estimated that the 2-midnight policy would increase expenditures by approximately $220 million in FY 2014 due to an expected net increase in inpatient encounters. We used our authority under section 1886(d)(5)(I)(i) of the Act to make a reduction of 0.2 percent to the standardized amount, the Puerto Rico standardized amount, and the hospital-specific payment rate, and we used our authority under section 1886(g) of the Act to make a reduction of 0.2 percent to the national capital Federal rate and the Puerto Rico-specific capital rate, in order to offset this estimated $220 million in additional IPPS expenditures in FY 2014. (In addition to an operating IPPS payment for each discharge, hospitals also receive a capital IPPS payment for each discharge so a net increase in the number of inpatient encounters also results in increased expenditures under the capital IPPS.)

II. Supplemental Notice Requesting Comments on the FY 2014 IPPS Rule

A. Overview

As noted in section I. of this notice with comment period, we estimated based on an actuarial model that the 2-midnight policy would increase IPPS expenditures by approximately $220 million in FY 2014 due to an expected net increase in inpatient encounters, as described in greater detail in an August 19, 2013 memorandum. (See Appendix A of this notice.)

Section II.B. of this notice with comment period provides additional details on the calculation of this estimate (that is, what we did) and section II.C. of this notice with comment period discusses the actuaries' assumptions, including why those assumptions were reasonable. We collectively refer to the calculations and assumptions as the actuarial ''model'' for estimating the financial impact of the policy change. Section II.D. of this notice with comment period discusses the status of an analysis currently being conducted by our actuaries of the claims experience since the implementation of the 2-midnight policy. We seek comment on all aspects of the model used by our actuaries, including but not limited to those for which we specifically request comment. We seek comment on, and will consider comments on, all aspects of the 0.2 percent reduction.

B. Calculation of the Impact of the 2-Midnight Policy

The task of modeling the impact of the 2-midnight policy on hospital payments begins with a recognition that some cases that were previously outpatient cases will become inpatient cases and vice versa. Therefore, our actuaries were required to develop a model that determined the net effect of the number of cases that would move in each direction.

In estimating the number of outpatient cases that would shift to the inpatient setting, we analyzed calendar year (CY) 2011 claims that included spending for observation care or a major procedure. For the purposes of the −0.2 percent estimate, CMS physicians defined observation care as Outpatient Prospective Payment System (OPPS) claims containing Healthcare Common Procedure Coding System (HCPCS) code ''G0378'', *Hospital observation service, per hour,* or HCPCS code ''G0379'' *Direct admission of patient for hospital observation care.* We used the difference between the first date of service for the HCPCS code (generally the first date that the service represented by that code was provided to the patient) and the ''claim through'' date (generally the last date any service on the claim was provided to the patient) to determine the length of the observation care. In this manner, we identified approximately 350,000 observation care stays of 2 midnights or more using the CY 2011 claims.

A list of the Ambulatory Payment Classifications (APCs) containing the major procedures used in the determination of the −0.2 percent estimate can be found in Appendix B of this notice with comment period. As with observation care, the difference between the first date of service for the HCPCS code and the claim through date was used to determine the length of the major procedure. We identified approximately 50,000 claims containing major procedures with stays lasting 2 midnights or more using the CY 2011 claims.

Combining the observation care and the major procedures resulted in approximately 400,000 claims for services of 2 midnights or more from the CY 2011 claims data.

For additional details on the identification of the outpatient claims, see Appendix C of this notice with comment period.

In estimating the number of inpatient stays that would shift to the outpatient setting, FY 2011 inpatient claims containing a surgical Medicare Severity Diagnosis Related Group (MS–DRG) were analyzed. The number of these stays that spanned less than 2 midnights, based on the length of stay, was approximately 360,000. FY 2009 and FY 2010 data were also analyzed and the results were consistent with the FY 2011 results.

For additional details on the identification of the inpatient claims, see Appendix D of this notice with comment period.

Our actuaries also assumed that payment under the OPPS would be 30 percent of the payment under the IPPS for encounters shifting between the two systems, and that the beneficiary is responsible for 20 percent of the Part B cost.

The number of short stay discharges (for this purpose, same day discharges and discharges crossing one or two midnights) represented about 28 percent of total discharges in FY 2011, and approximately 17 percent of total spending for the total discharges. The assumed net increase of 40,000

inpatient discharges (= 400,000 OPPS to IPPS—360,000 IPPS to OPPS) represented an increase of 1.2 percent in the number of short stay discharges. Taking 1.2 percent of 17 percent of total spending results in the estimate at the time of the FY 2014 IPPS/LTCH PPS rulemaking that the 2-midnight policy would result in an additional $290 million in inpatient expenditures, as shown for FY 2014 in the table ''Impact on Medicare Expenditures'' found in the memorandum in Appendix A of this notice. The estimates for the additional inpatient expenditures for FYs 2015 through 2018 can also be found in the table (for example, $320 million for FY 2015).

For the outpatient expenditure estimate, taking 30 percent (based on the assumption that payment under the OPPS would be 30 percent of the payment under the IPPS) of 80 percent (to account for the assumed 20 percent beneficiary responsibility) of the $290 million inpatient estimate results in approximately $70 million less outpatient expenditures. The estimates for the reduction in outpatient expenditures for FYs 2015 through 2018 can also be found in the table (For example, $80 million for FY 2015.)

The estimated $290 million increase in inpatient expenditures less the estimated $70 million decrease in outpatient expenditures yields the estimated net impact by our actuaries at the time of the FY 2014 IPPS/LTCH PPS rulemaking of an additional $220 million in expenditures in FY 2014 as a result of the 2-midnight policy. The estimated additional expenditures for FYs 2015 through 2018 can be similarly calculated.

Using the information contained in this section and the appendices to this notice, interested members of the public should be able to calculate the estimate by our actuaries of an additional $220 million in expenditures in FY 2014 as a result of the 2-midnight policy. (For interested members of the public who wish to perform this calculation, we highlight the discussion in Appendix D regarding the number of inpatient cases identified in the MedPAR data and the Integrated Data Repository.)

C. Discussion of the Assumptions Made in the Calculation of the Impact of the 2-Midnight Policy

As our actuaries stated in the August 2013 memorandum, the estimates depend critically on the assumed utilization changes in the inpatient and outpatient hospital settings. We discuss the assumptions underlying the estimates further in this section.

1. Estimated Outpatient Cases That Would Shift to the Inpatient Setting

As indicated previously, in estimating the number of outpatient cases that would shift to the inpatient setting, CY 2011 claims that included spending for observation care or a major procedure were analyzed. This was done in order to remove claims with diagnostic services or minor procedures that would be less likely to trigger an encounter in which there was a continuous stay. (See the discussion in Appendix C of this notice with comment period.)

For the purpose of the −0.2 percent estimate, observation care was defined as OPPS claims containing HCPCS ''G0378,'' *Hospital observation service,* per hour, or ''G0379'' *Direct admission of patient for hospital observation care.* At the time the −0.2 percent estimate was being developed, we were also examining establishing comprehensive APCs under the OPPS (for a summary of the results of this examination see the CY 2014 OPPS proposed rule (78 FR 43540)). One of the claims analyses that we developed for this purpose included service counts of G0378 and G0379 and significant procedures. Since this analysis included the universe of services of interest for the 2-midnight policy at that time, it was well-suited for use in the development of the −0.2 percent estimate as well. For a discussion of the data specifications for this claims analysis, and how it was subset for the 2-midnight analysis, see Appendix C of this notice with comment period.

However, in retrospect, using HCPCS G0378 and G0379 may have been an overly conservative definition of observation services, because not every use of observation services would be captured by the G-codes. As indicated in the Medicare Claims Processing Manual,[1] hospitals are required to report observation charges under the revenue center code ''0760'', *Treatment or observation room—general classification,* or ''0762'' *Treatment or observation room—observation room* regardless of whether or not the G-codes are billed.

We also note that the Office of the Inspector General (OIG) used this revenue center code definition of observation services in its report ''Hospitals' Use of Observation Stays and Short Inpatient Stays[2] (OEI–02–12–00040).

If we had defined observation services using revenue center codes 0760 and 0762 instead of HCPCS codes G0378 and G0379, we would have identified approximately 400,000 claims for observation services spanning 2 midnights or more (instead of 350,000) and we would have estimated approximately 450,000 cases shifting from the outpatient to the inpatient setting (400,000 claims for observation stays spanning more than 2 midnights and approximately 50,000 claims for major procedures) instead of the 400,000 cases used in the estimate. We seek comment on whether it would be more appropriate to define observation services using revenue center codes 0760 and 0762 rather than HCPCS codes G0378 and G0379.

Another consequence of the use of the claims analyses that we developed for the purpose of the comprehensive APCs involves the approach used to determine whether observation stays spanned 2 midnights or more. In general, in the claims analysis for comprehensive APC development, we examined the difference between the date of service for the primary HCPCS code on the claim and the claim through date. For the observation services in this analysis, we used the difference between first date of service for the observation service and the claim through date to determine the length of the observation case. However, in retrospect, as with the definition of observation services, this may have been an overly conservative approach to determining the length of the observation case. Under the 2-midnight policy, for purposes of determining whether the 2 midnight benchmark was met and, therefore, whether inpatient admission was generally appropriate, the expected duration of care includes the time the beneficiary spent receiving outpatient services within the hospital. This includes services such as observation services, treatments in the emergency department, and procedures provided in the operating room or other treatment area. It is not just the time spent receiving observation services. As such, it may have been more appropriate to have used the ''claim from'' date (in general the date that the beneficiary entered the hospital), rather than the first date that observation services were provided in order to determine when claims containing observation services spanned 2 midnights or more. If we had used such an approach when developing the original estimate, instead of approximately 350,000 claims with observation services spanning 2

[1] See section 290.2.1 in Chapter 4 of the Medicare Claims Processing Manual available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c04.pdf*)

[2] Available at *http://oig.hhs.gov/oei/reports/oei-02-12-00040.pdf.*

midnights or more, the estimate would have been approximately 430,000 claims under the HCPCS code G0378/G0370 definition of observation services and approximately 520,000 under the revenue center code 0760/0762 definition of observation services. When combined with our estimate of major procedures, we would have estimated as many as 570,000 cases shifting from the outpatient to the inpatient setting under this approach instead of the 400,000 cases used in the estimate. We seek comment on whether it would be more appropriate to have used the claim from date rather than the first date that observation services were provided in order to determine when claims containing observation services spanned 2 midnights or more.

2. Estimated Inpatient Cases That Would Shift to the Outpatient Setting

We believed some proportion of the inpatient cases under 2 midnights in the historical data would remain inpatient because we believed that behavioral changes by hospitals and admitting practitioners would mitigate some of the impact of cases shifting between the inpatient hospital setting and the outpatient hospital setting. The question was how to reasonably estimate what that proportion would be for purposes of modelling the impact of the 2-midnight policy. We believe that a model distinguishing between medical and surgical cases is a reasonable approach to use in determining what proportion of inpatient cases would remain in the inpatient setting and what proportion would shift to the outpatient setting.

Specifically, in estimating the number of inpatient stays that would shift to the outpatient setting, FY 2011 inpatient claims containing a surgical MS–DRG were analyzed. Our actuaries assumed that those spanning less than 2 midnights (other than those stays that were cut short by a death or transfer) would shift from the inpatient setting to the outpatient setting. Stays that were cut short by a death or transfer were excluded because under the 2-midnight policy those cases would generally be considered to be appropriately treated on an inpatient basis. (For a discussion of the data specifications for the inpatient claims analysis, see Appendix D of this notice.)

Claims containing medical MS–DRGs were excluded because, as stated in the August 2013 memorandum, ''it was assumed that these cases would be unaffected by the policy change.'' Our actuaries excluded medical MS–DRGs when developing the −0.2 percent estimate because they believed that due to behavioral changes by hospitals and admitting practitioners most inpatient medical encounters spanning less than 2 midnights before the current 2-midnight policy was implemented might be reasonably expected to extend past 2 midnights after its implementation and would thus still be considered inpatient. They believed that the clinical assessments and protocols used by physicians to develop an expected length of stay for medical cases were, in general, more variable and less defined than those used to develop an expected length of stay for surgical cases.

Evidence of this medical/surgical dichotomy is seen in proprietary utilization review tools such as the Milliman Care Guidelines, which are guidelines based originally on actuarial data, and InterQual, which are clinically oriented guidelines. Both tools reflect the same types of distinctions between medical and surgical cases that we assumed based on CMS medical staff's clinical judgment. Although all guidelines, and all surgeons, advise patients that individual patients vary in their post-operative courses, there are predictable post-operative courses that are based on such factors as whether or not the abdominal cavity or the pleural cavity are entered, the expected time for recovery from anesthesia, the expected time to resume urinary function, the expected time to resume bowel function, the expected time to regain mobility, and the typical period for common post-operative interventions. These are by no means absolute but are fairly well-defined, as evidenced by the surgeon's ability to generally inform the patient, within a day or so, how long the patient probably can expect to remain in the hospital if treatment goes well. Part of this decreased variance is due to the fact that the reason for admission, a specific surgical procedure, is well-defined.

Conversely, for medical admissions a single diagnosis typically covers a much broader spectrum of possibilities. Pneumonia may have different etiologies, with vastly different expected lengths of stay. A stroke may be minor, allowing a brief diagnostic workup to be followed by outpatient rehabilitation, or catastrophic, triggering a prolonged stay before stabilization and discharge. Chronic obstructive pulmonary disease (COPD) and congestive heart failure (CHF) may respond rapidly to medication adjustments or may result in Intense Care Unit (ICU) stays. Unlike the surgical procedure, the medical diagnosis does not imply a reasonably consistent set of activities. In fact, typical medical protocols are highly branched, with the initial portion of hospital care typically focused on diagnostics that serve to differentiate patient subsets that define treatments and simultaneously suggest different hospital courses. The increased variability in the medical protocols is influenced by the fact that, for planned surgical admissions, more of the branching takes place in the process of selecting a specific surgical intervention before the patient is admitted, while for medical admissions more of the branching takes place after admission.

For these reasons, the clinical judgment of CMS's medical staff supports our actuaries' estimate of the impact of the 2-midnight policy on program payments to hospitals.

3. Estimated IPPS/OPPS Cost Difference for Cases That Shift Between the IPPS and OPPS

Our actuaries assumed that the OPPS cost for services that shift between the OPPS and IPPS was 30 percent of the IPPS cost, and the beneficiary is responsible for 20 percent of the OPPS cost. The 30 percent is an assumption about the difference on average. While payment under the OPPS is on average less than payment under the IPPS for these cases, the key question is how much less on average? For any given case, the payment differential will vary. We note that when the OIG examined the payment differential between short inpatient stays and observation stays in their 2013 report ''Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries'' (OEI–02–12–00040), it found that on average Medicare paid nearly three times more for a short inpatient stay than an observation stay (p. 12). This is consistent with the 30 percent estimate used in the development of the −0.2 percent estimate. We seek comment on whether it is appropriate to utilize a 30 percent estimate.

D. Claims Experience Since the Implementation of the 2-Midnight Policy

Our actuaries are currently conducting an analysis of claims experience for FY 2014 and FY 2015 in light of available data, including the MedPAR data. Because that analysis is not yet complete, we are not proposing in this notice with comment period to reconsider the 0.2 percent reduction in the FY 2014 IPPS/LTCH PPS final rule based on the results of the claims analysis. However, we are seeking comment on whether we should await the completion of the actuaries' analysis of FY 2014 and FY 2015 data before resolution of this proceeding.

We note that any potential model revisions do not necessarily mean that the net result of the initial modelling, namely the ultimate −0.2 percent adjustment, was incorrect. As we have indicated since the −0.2 percent estimate was developed, the assumptions used for purposes of reasonably estimating overall impacts cannot be construed as absolute statements about every individual encounter. Under the original 2-midnight policy, our actuaries did not expect that every single surgical MS–DRG encounter spanning less than 2 midnights would shift to the outpatient setting, that every single medical MS–DRG encounter would remain in the inpatient setting, and that every single outpatient observation stay or major surgical encounter spanning more than 2 midnights would shift to the inpatient setting. However, for purposes of developing the −0.2 percent adjustment estimate under the original policy, a model where cases involving a surgical MS–DRG spanning less than 2 midnights in the historical data shifted to the outpatient setting, cases involving a medical MS–DRG spanning less than 2 midnights in the historical data remained in the inpatient setting, and outpatient observation stays and major surgical encounters spanning more than 2 midnights in the historical data shifted to the inpatient setting yielded a reasonable estimate of the net effect of the 2-midnight policy when it was adopted. To the extent the actual experience might vary for each of the individual assumptions, our actuaries estimated that the total net effect of that variation would not significantly impact the estimate.

There were also factors that could not be anticipated at the time of the initial modelling that may influence the actual experience, such as the prohibition on Recovery Auditor post-payment reviews that became effective October 1, 2013. This prohibition might have affected hospital behavior in unexpected ways.

Our actuaries will continue to review the claims experience for FY 2014 and subsequent years under the 2-midnight policy to evaluate the assumptions underlying the original estimate. As we indicated in the CY 2016 OPPS/ASC final rule, we will take the reviews into account during future rulemaking, including potential future rulemaking on the issue of whether or not the policy change that we adopted for the medical review of inpatient hospital admissions under Medicare Part A described in the CY 2016 OPPS final rule will have a differential impact on expenditures compared to the original policy. Although our analysis of the historical data since the implementation of the 2-midnight policy is not yet complete, and we do not propose to reconsider the reduction in light of that analysis at this time, we are including this discussion in this notice because we received many comments on the CY 2016 OPPS proposed rule asserting that the claims data since the adoption of the original 2-midnight policy is inconsistent with our original −0.2 percent estimate. We continue to invite comment on this issue. As indicated in the CY 2016 OPPS final rule, we intend to respond to all public comments regarding the validity of the original −0.2 percent adjustment that we received in response to the CY 2016 OPPS proposed rule as part of these Shands remand proceedings and publish a final notice by March 18, 2016.

We elected to promulgate the -0.2 percent adjustment for the reasons described in the FY 2014 IPPS/LTCH PPS proposed and final rules and elaborated upon in this notice with comment period. We request comment on all aspects of that decision, including but not limited to the information, assumptions, and analyses supporting the adjustment.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IV. Response to Comments

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

Dated: November 20, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 24, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

Appendix A

BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N3-01-21
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of the Actuary

DATE: August 19, 2013

SUBJECT: Estimated Financial Effects of 2 Midnight Policy

This memorandum summarizes the Office of the Actuary's financial estimate for clarifying inpatient vs. outpatient hospital services when all stays which span 2 midnights will be presumed to be inpatient. Recent events related to this issue and relevant to the discussion are described below.

Based on longstanding CMS policy, if a hospital submitted a claim for Part A inpatient services and that claim was denied because the service was (or should have been) provided in an outpatient setting, then the hospital could not subsequently submit a claim for Part B reimbursement.3 A recent decision by an Administrative Law Judge (ALJ), which has been confirmed by the Departmental Appeals Board, authorizes Part B re-billing for all such denied Part A claims that have been appealed and upheld by an ALJ. CMS addressed the issue of re-billing, as summarized below.

- An Administrator Ruling allowed providers to automatically re-bill Part B in such cases, starting in January of 2013 and ending in September of 2013, without having to go through the appeals process.
- Regulatory change would restrict re-billing to only those instances where the re-billed claim for Part B services was submitted within 12 months of the original date of service. This change is assumed to take effect beginning in October of 2013.
- Regulatory change clarifying that if a hospital stay spanned 2 midnights then it was presumed to be an inpatient stay. This change is assumed to take effect beginning in October of 2013.

The ALJ decision is estimated to increase Medicare expenditures, in part because of the cost of the additional Part B payments but also due to potential changes in how providers classify short-stay services, given the availability of Part B reimbursement should their Part A claims be denied. The Administrator ruling is assumed to further increase expenditures, since providers could re-bill Part B without the need to appeal a Part A denial. The 12-month restriction imposed by the regulation would greatly limit the circumstances in which a hospital could re-bill and thereby substantially reduce the number of questionable Part A claims, largely offsetting the higher costs arising from

3 Certain ancillary services could be billed under Part B, but not the principal service itself.

the ALJ decision and the proposed Administrator ruling. Therefore, the net impact of the ALJ decision, Administrator ruling, and the 12-month timely filing restriction is negligible.

The 2 midnight admission policy is estimated to increase Medicare expenditures due to an assumed net increase in inpatient hospital admissions resulting from a shift in cases from the outpatient setting, since providers are only required to keep a beneficiary over 2 midnights in order for the stay to be considered inpatient. In other words, it is assumed that some cases would switch from inpatient to outpatient and some from outpatient to inpatient, but the net effect is an assumed increase in inpatient hospital admissions. Several assumptions were made to estimate the financial impact of this policy change, and the key assumptions are described below.

- These impacts are based on the assumptions and projections from the President's FY 2013 Budget.
- In estimating the number of outpatient cases that would shift to the inpatient setting, claims that included spending for observation care or a major procedure were analyzed. Outpatient stays that were shorter than 2 midnights and those that were not for observation care or for a major procedure were excluded because it was assumed that these cases would be unaffected by the policy change. The number of these stays that spanned 2 or more midnights, based on the dates of service, was approximately 400,000.
- In estimating the number of inpatient stays that would shift to the outpatient setting, claims containing a surgical MS-DRG were analyzed. Claims containing medical MS-DRGs and those that resulted in death or a transfer were excluded because it was assumed that these cases would be unaffected by the policy change. The number of these stays that spanned less than 2 midnights, based on the length of stay, was approximately 360,000.
- These estimates were primarily based on FY 2011 data. However, FY 2009 and FY 2010 data were also analyzed and the results were consistent with the FY 2011 results.
- The Part B cost for services that should have been provided in the outpatient setting is assumed to be roughly 50 percent of the Part A cost when provided in the inpatient setting, and the beneficiary is responsible for 20 percent of the Part B cost. Consequently, when an inpatient admission is denied, the cost to Part B is substantially lower than the Part A cost.
- While there is a certain degree of uncertainty surrounding any cost estimate, we have determined that the methodology, data, and assumptions used are reasonable for the purpose of estimating the overall impact of the proposed 2-midnight policy. It is important to note that the assumptions used for purposes of reasonably estimating the overall impact should not be construed as absolute statements about every individual encounter. For example, not every single surgical MS-DRG spanning less than 2 midnights will shift to outpatient and not every single outpatient observation stay or major surgical encounter spanning more than 2 midnights will shift to inpatient.
- The number of short stay discharges represents about 28 percent of total discharges, and approximately 17 percent of total spending for these discharges. The assumed net increase of 40,000 discharges represents an increase of 1.2 percent in the number of short stay discharges.
- There would likely be an increase in the utilization of SNF services since a portion of the cases that shift from outpatient to inpatient could result in a SNF stay. Based on the 2011 Medicare & Medicaid Statistical Supplement, about 15 percent of 2010 inpatient stays resulted in a follow-up SNF stay, with an average length of stay of about 27 days and an estimated cost to Medicare of approximately $11,000 per stay. Since these shifted cases don't currently have an

associated SNF stay, they are likely to be for healthier beneficiaries; therefore, it was assumed that only 10 percent of these shifted cases would result in a follow-up SNF stay. In addition, the average payment per SNF stay for these cases is assumed to be 30 percent less than the average, which is the combined effect of assumed shorter lengths of stay and lower case-mix.

The table below contains the impact on Medicare spending for both Part A and Part B, as a result of the 2 midnight policy. These changes are mainly the result of the changes in utilization of inpatient and outpatient hospital services assumed for each. The amounts are shown in millions for fiscal years 2014 through 2018.

Impact on Medicare expenditures
(in millions)

Fiscal year	Inpatient	Outpatient	SNF	Managed care	Part B premium offset	Total
2014	$290	−$70	$40	$70	$20	$350
2015	320	−80	40	70	30	380
2016	340	−80	50	60	30	400
2017	360	−90	60	60	30	420
2018	390	−90	60	60	30	450

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

A portion of this additional cost is to be offset by applying an adjustment factor to the standardized rates, as explained in the final rule for the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status (CMS-1599-F, CMS-1455-F). The adjustment would be only for those costs related to hospital care which are represented in the table above by the sum of the inpatient and outpatient columns. This amount is $220 million in FY 2014, which translates to a 0.2 percent reduction in the standardized amounts.

Please note the following caveats relating to these estimates. The actual costs or savings will depend substantially on possible changes in behavior by hospitals and the RACs, and such changes cannot be anticipated with certainty. While the estimates are not especially sensitive to many of the assumptions outlined above, they do depend critically on the assumed utilization changes in the inpatient and outpatient hospital settings. While we believe that these assumptions are reasonable, relatively small changes would have a disproportionate effect on the estimated net costs. For this reason, these estimates are subject to a much greater degree of uncertainty than usual, and actual results could differ significantly from these estimates. Please let us know if you have any questions about this information.

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Appendix B

List of APCs Containing Major Procedures For Purposes of the 2 Midnight Estimate

APC—APC Description
0005—Level II Needle Biopsy/ Aspiration Except Bone Marrow
0007—Level II Incision & Drainage
0008—Level III Incision and Drainage
0012—Level I Debridement & Destruction
0017—Level V Debridement & Destruction
0019—Level I Excision/Biopsy
0020—Level II Excision/Biopsy
0021—Level III Excision/Biopsy
0022—Level IV Excision/Biopsy
0028—Level I Breast Surgery
0029—Level II Breast Surgery
0030—Level III Breast Surgery
0037—Level IV Needle Biopsy/ Aspiration Except Bone Marrow
0041— Arthroscopy
0042—Level II Arthroscopy
0045—Bone/Joint Manipulation Under Anesthesia
0047—Arthroplasty without Prosthesis
0048—Level I Arthroplasty or Implantation with Prosthesis
0049—Level I Musculoskeletal Procedures Except Hand and Foot
0050—Level II Musculoskeletal Procedures Except Hand and Foot
0051—Level III Musculoskeletal Procedures Except Hand and Foot
0052—Level IV Musculoskeletal Procedures Except Hand and Foot
0053—Level I Hand Musculoskeletal Procedures
0054—Level II Hand Musculoskeletal Procedures
0055—Level I Foot Musculoskeletal Procedures
0056—Level II Foot Musculoskeletal Procedures
0057—Bunion Procedures
0062—Level I Treatment Fracture/ Dislocation
0063—Level II Treatment Fracture/ Dislocation
0064—Level III Treatment Fracture/ Dislocation
0069—Thoracoscopy
0074—Level IV Endoscopy Upper Airway
0075—Level V Endoscopy Upper Airway
0076—Level I Endoscopy Lower Airway
0080—Diagnostic Cardiac Catheterization
0082—Coronary or Non-Coronary Atherectomy
0083—Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization
0085—Level II Electrophysiologic Procedures
0086—Level III Electrophysiologic Procedures
0088—Thrombectomy
0089—Insertion/Replacement of Permanent Pacemaker and Electrodes
0090—Level I Insertion/Replacement of Permanent Pacemaker
0091—Level II Vascular Ligation
0092—Level I Vascular Ligation
0093—Vascular Reconstruction/Fistula Repair without Device
0103—Miscellaneous Vascular Procedures
0104—Transcatheter Placement of Intracoronary Stents
0105—Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices
0106—Insertion/Replacement of Pacemaker Leads and/or Electrodes
0107—Insertion of Cardioverter-Defibrillator Pulse Generator
0108—Insertion/Replacement/Repair of Cardioverter-Defibrillator System
0113—Excision Lymphatic System
0114—Thyroid/Lymphadenectomy Procedures
0115—Cannula/Access Device Procedures
0121—Level I Tube or Catheter Changes or Repositioning
0130—Level I Laparoscopy
0131—Level II Laparoscopy
0132—Level III Laparoscopy
0135—Level III Skin Repair
0136—Level IV Skin Repair
0137—Level V Skin Repair
0148—Level I Anal/Rectal Procedures
0149—Level III Anal/Rectal Procedures
0150—Level IV Anal/Rectal Procedures
0152—Level I Percutaneous Abdominal and Biliary Procedures
0153—Peritoneal and Abdominal Procedures
0154—Hernia/Hydrocele Procedures
0160—Level I Cystourethroscopy and other Genitourinary Procedures
0161—Level II Cystourethroscopy and other Genitourinary Procedures
0162—Level III Cystourethroscopy and other Genitourinary Procedures
0163—Level IV Cystourethroscopy and other Genitourinary Procedures
0166—Level I Urethral Procedures
0168—Level II Urethral Procedures
0169—Lithotripsy
0174—Level IV Laparoscopy
0181—Level II Male Genital Procedures
0183—Level I Male Genital Procedures
0184—Prostate Biopsy
0190—Level I Hysteroscopy
0192—Level IV Female Reproductive Proc
0193—Level V Female Reproductive Proc
0195—Level VI Female Reproductive Procedures
0202—Level VII Female Reproductive Procedures
0208—Laminotomies and Laminectomies
0220—Level I Nerve Procedures
0221—Level II Nerve Procedures
0224—Implantation of Catheter/ Reservoir/Shunt
0227—Implantation of Drug Infusion Device
0229—Level II Endovascular Revascularization of the Lower Extremity
0233—Level III Anterior Segment Eye Procedures
0234—Level IV Anterior Segment Eye Procedures
0237—Level II Posterior Segment Eye Procedures
0238—Level I Repair and Plastic Eye Procedures
0239—Level II Repair and Plastic Eye Procedures
0240—Level III Repair and Plastic Eye Procedures
0241—Level IV Repair and Plastic Eye Procedures
0242—Level V Repair and Plastic Eye Procedures
0243—Strabismus/Muscle Procedures
0244—Corneal and Amniotic Membrane Transplant
0246—Cataract Procedures with IOL Insert
0249—Cataract Procedures without IOL Insert
0252—Level III ENT Procedures
0253—Level IV ENT Procedures
0254—Level V ENT Procedures
0255—Level II Anterior Segment Eye Procedures
0256—Level VI ENT Procedures
0259—Level VII ENT Procedures
0293—Level VI Anterior Segment Eye Procedures
0319—Level III Endovascular Revascularization of the Lower Extremity
0384—GI Procedures with Stents
0387—Level II Hysteroscopy
0415—Level II Endoscopy Lower Airway
0419—Level II Upper GI Procedures
0422—Level III Upper GI Procedures
0423—Level II Percutaneous Abdominal and Biliary Procedures
0425—Level II Arthroplasty or Implantation with Prosthesis
0427—Level II Tube or Catheter Changes or Repositioning
0428—Level III Sigmoidoscopy and Anoscopy
0429—Level V Cystourethroscopy and other Genitourinary Procedures
0434—Cardiac Defect Repair
0648—Level IV Breast Surgery
0651—Complex Interstitial Radiation Source Application
0653—Vascular Reconstruction/Fistula Repair with Device
0654—Level II Insertion/Replacement of Permanent Pacemaker
0655—Insertion/Replacement/ Conversion of a Permanent Dual Chamber Pacemaker or Pacing

0656—Transcatheter Placement of Intracoronary Drug-Eluting Stents
0672—Level III Posterior Segment Eye Procedures
0673—Level V Anterior Segment Eye Procedures
0674—Prostate Cryoablation
0687—Revision/Removal of Neurostimulator Electrodes
0688—Revision/Removal of Neurostimulator Pulse Generator Receiver

Appendix C

Discussion of the Outpatient Data

This Appendix provides additional detail on how we identified outpatient claims for observation services or a major procedure spanning 2 midnights or more for purposes of estimating the shift in outpatient cases.

The comprehensive APC analysis that also formed the basis for the 2 midnight analysis was performed using 2011 OPPS claims of bill type 13x extracted from the Standard Analytic File processed through December 31, 2011 with service line charges converted to costs per the usual OPPS cost modeling logic. (A description of the cost modeling logic can be found in the claims accounting document for each year of OPPS rulemaking and is available on our Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.) Similar conclusions regarding the −0.2 percent estimate can be drawn by analyzing the OPPS Limited Data Set rather than the Standard Analytic File. The CMS Web site at *https://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/HospitalOPPS.html* provides information about ordering the OPPS Limited Data Set containing the outpatient hospital data. In order to facilitate a claims analysis using the claim from date and the claim through date a new field has been added to the OPPS Limited Data Set.

Hospital OP claims do not readily distinguish between claims based on services provided while the beneficiary physically stayed at the hospital and claims where the beneficiary received recurring services on successive days while leaving the hospital between services. Since only continuous stays apply for this analysis, certain assumptions had to be made to indirectly estimate the body of claims for continuous stays. Claims were trimmed to only those whose full span of coverage (the difference of claim-through-date and claim-from-date) was less than 7 days. Claims with longer than a 7 day span were excluded as unlikely to represent continuous overnight stays. Claims were then subset to those containing observation services or a significant procedure, as observation services are reported differently in those two subgroups. To further remove recurring services during this subsetting, claims that did not fall into one of the following were removed from the analysis:

- Claims containing G0378 (''Hospital observation per hr'') and a medical visit procedure code (status indicator of ''V'');
- Claims containing G0379 (''Direct refer hospital observ''), considered to be ''medical claims;''
- Claims containing a significant OPPS procedure code (status indicator of ''S'' or ''T'') that received Medicare payment, considered to be ''surgical claims.''

Next, the highest cost coded services on non-observation claims (those without G0379 or without G0378 and a medical visit procedure) were identified. Non-observation claims where the highest cost procedure was not a C-code (Temporary Hospital Outpatient PPS), a J-code (non-orally administered medication and chemotherapy drugs), a significant OPPS procedure code (status indicator of ''S'' or ''T''), or a medical visit procedure code (status indicator of ''V'') were removed from the analysis. This removed non-observation claims where the highest cost service was not typical for a claim associated with a major procedure.

Following these steps, a principal procedure representing the primary service driving the claim's overall utilization was identified for each remaining claim. For observation claims containing both G0379 and G0378 with a medical visit procedure, the principal procedure was identified as G0379 or G0378 depending on which code reports a higher line-item cost. Otherwise, observation claims were assigned a principal procedure of G0379 and G0378 depending on whether G0379 or G0378 with a medical visit procedure were respectively reported.

For non-observation claims, the principal procedure was identified as the claim's significant OPPS procedure code (status indicator of ''S'' or ''T'') with the highest line-item cost. Non-observation claims where the earliest service date of the principal procedure occurred more than 5 days before or on the same date as the claim-through-date were removed from the analysis, as these were assumed to represent recurring services. Additionally, non-observation claims were trimmed to those where the principal procedure occurs on only a single service date, thus removing any claim that contains major recurring services and ensuring that the stay is initiated with a single instance of the major procedure.

To remove aberrant claims, each claim's non-observation total claim cost was then calculated by summing the line-item costs for all coded services and all OPPS packaged revenue centers on the claim. Each claim's span of coverage was also calculated as the number of days between the provision of the principal service and the claim's through-date. The geometric mean cost was calculated for each observation or non-observation principal procedure using the claims' total cost, and those claims with unreasonable costs (That is, claim costs above 100 times or below 1 percent of the principal procedure geometric mean cost) were trimmed from the analysis.

For purposes of the 2 midnight analysis, we then further subset the data to APCs having a status indicator of ''T'' in order remove services which were not relevant for the 2 midnight analysis that is, to remove those services that were more likely to represent diagnostic services or minor procedures interjected into a series of recurring services, and were less likely to trigger a ''surgical'' episode in which a continuous stay followed the procedure. For similar reasons, our medical officers also removed some of the remaining APCs based on clinical judgment that those services were unlikely to be indicative of a continuous protracted hospital stay. The full list of OPPS status indicators and their definitions is published in the OPPS/ASC proposed and final rules each year, available on our Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.* The final list of major procedure APCs used in the development of the −0.2 percent estimate can be found in Appendix B.

As described in section II.D of this notice, we have also been performing an analysis of the claims experience since the implementation of the 2-midnight policy. This analysis has used claims data from the OPPS Limited Data Set. We have also been examining similar data from our Integrated Data Repository (see *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/* for a description of the IDR). For the purpose of this analysis, we have used the following claim selection criteria: the third position of the provider number group was equal to ''0'' (short-term hospital) and the first 2 positions of the provider number were not equal to ''21'' (excludes Maryland hospitals.)

We seek comment on the appropriate outpatient data source to use for the −0.2 percent estimate and any data trims and claims selection criteria that we should apply to the data.

Appendix D

Discussion of the Inpatient Data

This Appendix provides additional detail on how we identified inpatient stays spanning less than 2 midnights for surgical MS–DRGs for purposes of estimating the shift in inpatient cases.

The inpatient data used in the original −0.2 estimate was based on data from the CMS Integrated Data Repository (IDR) (see *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/* for a description of the IDR). The CMS Web site at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/* provides information about ordering the ''MedPAR Limited Data Set (LDS)-Hospital (National)'' containing the publicly available inpatient hospital data. At the time the original −0.2 percent estimate was developed, we believed similar conclusions regarding the −0.2 percent estimate could be drawn using either the IDR or the publicly available inpatient data files. However, we did not verify this at the time.

When we now compare the number of inpatient stays less than 2 midnights for surgical MS–DRGs (excluding deaths and transfers) from the FY 2011 IDR data available to us at the time of the original −0.2 estimate (claims processed through June of 2013) to the number from the FY 2011 MedPAR data (claims processed through March of 2013), we get

approximately 360,000 stays from the IDR data and approximately 380,000 stays from the MedPAR data. Further complicating a current analysis relative to the analysis performed at that time, when we examine the FY 2011 IDR data available to us now (claims processed through October 2015) compared to when the original −0.2 percent estimate was developed (claims processed through June 2013), we get approximately 340,000 stays instead of the originally estimated 360,000 stays, which we suspect is at least partly driven by subsequent claim denials for these cases that have occurred since the data was examined for the original −0.2 percent estimate. Because the historical MedPAR data for a given fiscal year is not generally refreshed after it is created, unlike the IDR which is refreshed, there is no analogous number to the 340,000 for the FY 2011 MedPAR.

In determining the 380,000 number from the FY 2011 MedPAR, the following inpatient claim selection criteria and data trims were applied to the data. We selected FY 2011 MedPAR claims based on a FY 2011 date of discharge where the National Claims History (NCH) claim type code was equal to ''60'' (inpatient hospital), the third position of the provider number group was equal to ''0'' (short-term hospital), the first 2 positions of the provider number were not equal to ''21'' (excludes Maryland hospitals), the destination discharge code was not equal to ''30'' (excludes still a patient), the special unit code was blank (excludes, for example, PPS exempt units), the GHO paid code was not equal to ''1'' (a group health organization has not paid the provider), the total charge amount was greater than 0, and the IME amount was not equal to the DRG price amount (indicating it was not a managed care claim).

As described in section II.D of this notice, we have also been performing an analysis of the claims experience since the implementation of the 2-midnight policy. This analysis has used data from the publicly available MedPAR file and the IDR.

We seek comment on the appropriate inpatient data source to use for the −0.2 percent estimate and any data trims and claims selection criteria that we should apply to the data.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Building Bridges and Bonds (B3) Study: Data Collection.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), Office of Planning, Research and Evaluation (OPRE) proposes to collect information as part of the Building Bridges and Bonds (B3) study. B3 will inform policymakers, program operators, and stakeholders about effective ways for fatherhood programs to support fathers in their parenting and employment. In particular, partnering with programs that serve low-income fathers to promote responsible fatherhood, the B3 study will examine the effectiveness of strategies used to (1) engage fathers in program activities, (2) develop and support parenting and co-parenting skills, and (3) advance the employment of disadvantaged fathers. B3 will test innovative, evidence-informed approaches that will be added to the core components of fatherhood programs and will reflect the most recent developments in behavioral science, adult skill-building, child development, and other relevant disciplines. The study will include up to six sites and specific interventions will vary by site.

B3 includes an impact evaluation and a process study. The impact evaluation will involve randomly assigning individuals to a treatment or comparison condition and comparing key outcomes. In addition, the study will collect information on employment, criminal justice and child support outcomes from administrative records. These data will be used to estimate the effects of the parenting or employment intervention on a range of outcomes including employment; earnings; child support; father/child contact, shared activities, and relationship quality; father's commitment to his child, parenting skills, and parenting efficacy; co-parenting relationship quality; and criminal justice outcomes.

The process study will describe and document each newly established intervention and how it operated to provide insight into the treatment differentials and the context for interpreting findings of the impact study. The process study will also highlight lessons to the field including what it takes to engage participants, the challenges sites face when implementing the parenting or employment intervention, and the participants' perspectives on whether the program components offered met their needs.

Data collection instruments for the B3 study include the following: (1) Screening for program eligibility to help ensure that only eligible fathers enroll in the study.

(2) nFORM management information system (MIS) to record study and participation information. Note: Only B3-specific burden is included with this request. All Responsible Fatherhood Grantees (funded by the ACF Office of Family Assistance) are required to use nFORM. nFORM is being developed by the Fatherhood and Marriage Local Evaluation and Cross-site (FaMLE Cross-site) Project and burden for these sites are captured under OMB #0970–0460. (3) Applicant characteristics and program operations data for one non-grantee site. We expect most of the B3 sites will be federally funded Responsible Fatherhood grantees, but it is possible that one site will not and therefore, this request includes burden for one site to use nFORM. (4) Baseline and follow-up surveys for the impact study. There will be two versions of each survey, specific to the intervention tested. (5) Baseline and follow-up questionnaires, interviews, focus groups, and surveys to inform the process study; these will also be specific to the intervention tested.

The sites that are part of the B3 study will use a slightly modified version of nFORM that includes B–3 specific information, such as: (1) B3-specific enrollment data (2) B3-specific information about focal child and co-parent in in sites testing a parenting intervention, and (3) B3 tracking of child and co-parent attendance in services with the father for program group members in sites testing a parenting intervention.

RESPONDENTS: Fathers seeking services from one of the six Responsible Fatherhood Programs in the B3 study and staff members working at the B3 sites.