BIPA and section 732 of the MMA, which directed us to continue payment to independent laboratories for the TC of physician pathology services for hospital patients for a 2-year period beginning on January 1, 2001 and for CYs 2005 and 2006, respectively. In the CY 2007 PFS final rule with comment period (71 FR 69788), we amended § 415.130 to provide that, for services furnished after December 31, 2006, an independent laboratory may not bill the carrier for the TC of physician pathology services furnished to a hospital inpatient or outpatient. However, section 104 of the MIEA–TRHCA continued payment to independent laboratories for the TC of physician pathology services for hospital patients through CY 2007, and section 104 of the MMSEA further extended such payment through the first 6 months of CY 2008.

Section 136 of the MIPPA extended the payment through CY 2009. Section 3104 of the Affordable Care Act amended the prior legislation to extend the payment through CY 2010. Section 105 of the MMEA extended the payment through CY 2011. Subsequent to the publication of the CY 2012 PFS final rule with comment period, section 305 of the Temporary Payroll Tax Cut Continuation Act of 2011 extended the payment through February 29, 2012 and section 3006 of the Middle Class Tax Relief and Job Creation Act of 2012 extended the payment through June 30, 2012.

2. Revisions to Payment for TC of Certain Physician Pathology Services

In the CY 2012 PFS final rule with comment period, we finalized our policy that an independent laboratory may not bill the Medicare contractor for the TC of physician pathology services furnished after December 31, 2011, to a hospital inpatient or outpatient (76 FR 73278 through 73279, 73473). As discussed above, subsequent to publication of that final rule with comment period, Congress acted to continue payment to independent laboratories through June 30, 2012. Therefore, the policy that we finalized in the CY 2012 PFS final rule with comment period was superseded by statute for 6 months. To be consistent with the statutory changes and our current policy, we proposed conforming changes to § 415.130(d) such that we continued payment under the PFS to independent laboratories furnishing the TC of physician pathology services to fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital on or before June 30, 2012 (77 FR 44763). Independent laboratories may not bill the Medicare contractor for the TC of physician pathology services furnished after June 30, 2012, to a hospital inpatient or outpatient. We received no public comments on the proposed conforming changes so we are finalizing the revisions to § 415.130(d) without modification.

G. Therapy Services

1. Outpatient Therapy Caps for CY 2013

Section 1833(g) of the Act applies annual, per beneficiary, limitations (therapy caps) on expenses considered incurred for outpatient therapy services under Medicare Part B. There is one therapy cap for outpatient occupational therapy (OT) services and another separate therapy cap for physical therapy (PT) and speech-language pathology (SLP) services combined. Although therapy services furnished in an outpatient hospital setting have been exempt from the application of the therapy caps, section 3005(b) of the MCTRJCA amended section 1833(g) of the Act to include therapy services furnished in an outpatient hospital setting in the therapy caps. This provision is in effect from October 1, 2012 through December 31, 2012.

The therapy cap amounts are updated each year based on the Medicare Economic Index (MEI). The annual change in the therapy cap amount for CY 2013 is computed by multiplying the cap amount for CY 2012 by the MEI for CY 2013 and rounding to the nearest $10. This amount is added to the CY 2012 cap, which is $1,880, to obtain the CY 2013 cap amount. The MEI for CY 2013 is 0.8 percent, resulting in a therapy cap amount for CY 2013 of $1,900.

An exceptions process to the therapy caps has been in effect since January 1, 2006. Since originally authorized by section 5107 of the Deficit Reduction Act (DRA), which amended section 1833(g)(5) of the Act, the exceptions process for the therapy caps has been extended through subsequent legislation (MIEA–TRHCA, MMSEA, MIPPA, the Affordable Care Act, MMEA, and TPTCCA). Last amended by section 3005 of the MCTRJCA, the Agency's authority to provide for an exception process to therapy caps expires on December 31, 2012. To request an exception to the therapy caps, therapy suppliers and providers use the KX modifier on claims for services after the beneficiary's services for the year have exceeded the therapy cap. Use of the KX modifier indicates that the services are reasonable and necessary and that there is documentation of medical necessity in the beneficiary's medical record.

Section 3005 of the MCTRJCA also required two additional changes to Medicare policies for outpatient therapy services. Effective for services furnished from October 1 through December 31, 2012, after a beneficiary's incurred expenses for PT and SLP services combined exceed the threshold of $3,700 during the calendar year, section 1833(g)(5)(C) of the Act, as amended by 3005(a)(5) of the MCTRJCA, requires that we apply a manual medical review process as part of the therapy caps exceptions process. Similar to the therapy caps, there is a separate $3,700 threshold for OT services. All requests for exceptions to the therapy caps for services after the $3,700 threshold is reached are subject to manual medical review. The manual medical review process is being phased in over a 3-month period. Unlike the therapy caps, exceptions are not automatically granted for therapy services above the $3,700 threshold based upon the therapist's determination that they services are reasonable and necessary. To request an exception to the therapy caps for services after the threshold is reached, the provider sends a request for an exception to the Medicare contractor. The contractor then uses the coverage and payment requirements contained within Pub. 100–02, Medicare Benefit Policy Manual, section 220 and applicable medical review guidelines, and any relevant local coverage determinations to make decisions as to whether an exception is approved for the services. For more information on the manual medical review process, go to *www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/TherapyCap.html.*

2. Claims-Based Data Collection Strategy for Therapy Services

a. Introduction

Section 3005(g) of the MCTRJCA requires CMS to implement, beginning on January 1, 2013, ''* * * a claims-based data collection strategy that is designed to assist in reforming the Medicare payment system for outpatient therapy services subject to the limitations of section 1833(g) of the Act. Such strategy shall be designed to provide for the collection of data on patient function during the course of therapy services in order to better understand patient condition and outcomes.''

b. History/Background

In 2011, more than 8 million Medicare beneficiaries received outpatient therapy services, including

physical therapy (PT), occupational therapy (OT), and speech-language-pathology (SLP). Medicare payments for these services exceeded $5.8 billion. Between 1998–2008, Medicare expenditures for outpatient therapy services increased at a rate of 10.1 percent per year while the number of Medicare beneficiaries receiving therapy services only increased by 2.9 percent per year. Although a significant number of Medicare beneficiaries benefit from therapy services, the rapid growth in Medicare expenditures for these services has long been of concern to the Congress and the Agency. To address this concern, efforts have been focused on developing Medicare payment incentives that encourage delivery of reasonable and necessary care while discouraging overutilization of therapy services and the provision of medically unnecessary care. A brief review of these efforts is useful in understanding our policy for CY 2013.

(1) Therapy Caps

Section 4541 of the Balanced Budget Act of 1997 (Pub. L. 105–33) (BBA) amended section 1833(g) of the Act to impose financial limitations on outpatient therapy services (the ''therapy caps'' discussed above) in an attempt to limit Medicare expenditures for therapy services. Prior to the BBA amendment, these caps had applied to services furnished by therapists in private practice, but the BBA expanded the caps effective January 1, 1999, to include all outpatient therapy services except those furnished in hospital outpatient departments. Since that time, the Congress has amended the statute several times to impose a moratorium on the application of the caps or has required us to implement an exceptions process for the caps. The therapy caps have only been in effect without a moratorium or an exceptions process for less than 2 years. (See the discussion about the therapy cap exceptions process above.) Almost from the inception of the therapy caps, Congress and the Agency have been exploring potential alternatives to the therapy caps.

(2) Multiple Procedure Payment Reduction (MPPR)

In the CY 2011 PFS final rule with comment period (75 FR 73232–73242), we adopted a MPPR of 25 percent applicable to the practice expense (PE) component of the second and subsequent therapy services furnished to a beneficiary when more than one of these services is furnished in a single session. This reduction applies to nearly 40 therapy service codes. (For a list of therapy service codes to which this policy applies, see Addendum H.) The Physician Payment and Therapy Relief Act of 2010 (PPATRA) subsequently revised the reduction to 20 percent for the second and subsequent therapy services furnished to a beneficiary in an office setting, leaving the 25 percent reduction in place for therapy services furnished to a beneficiary in institutional settings. We adopted this MPPR as part of our directive under section 1848(c)(2)(K) of the statute, as added by section 3134(a) of the Affordable Care Act, to identify and evaluate potentially misvalued codes. By taking into consideration the expected efficiencies in direct PE resources that occur when services are furnished together, this policy results in more appropriate payment for therapy services. Although we did not adopt this MPPR policy specifically as an alternative to the therapy caps, paying more appropriately for combinations of therapy services that are commonly furnished in a single session reduces the number of beneficiaries impacted by the therapy caps in a given year. For more details on the MPPR policy, see section II.B.4. of this final rule with comment period.

(3) Studies Performed

The therapy cap is a uniform dollar amount that sets a limit on the total value of services furnished unrelated to the specific services furnished or the beneficiary's condition or needs. A uniform cap does not deter unnecessary care or encourage efficient practice for low complexity beneficiaries. In fact, it may even encourage the provision of services up to the level of the cap. Conversely, a uniform cap without an exceptions process restricts necessary and appropriate care for certain high complexity beneficiaries. Recognizing these limitations in a uniform dollar value cap, we have been studying therapy practice patterns and exploring ways to refine payment for these services as an alternative to therapy caps.

On November 9, 2004, the Secretary delivered the Report to Congress, as required by the BBA as amended by the BBRA, ''Medicare Financial Limitations on Outpatient Therapy Services.'' This report included two utilization analyses. Although these analyses provided details on utilization, neither specifically identified ways to improve therapy payment. In the report, we indicated that further study was underway to assess alternatives to the therapy caps. The report and the analyses are available on the CMS Web site at *www.cms.gov/TherapyServices/*.

Since 2004, we have periodically updated the utilization analyses and posted other reports on the CMS Web site. These reports highlighted the expected effects of limiting services in various ways and presented plans to collect data about beneficiary condition, including functional limitations, using available tools. Through these efforts, we have made progress in identifying the types of outpatient therapy services that are billed to Medicare, the demographics of the beneficiaries who utilize these services, the HCPCS codes used to bill the services, the allowed and paid amounts of the services, the providers of these services, the therapy utilization patterns among states in which the services are furnished, and the type of practitioner furnishing services.

From these and other analyses in our ongoing research effort, we have concluded that without the ability to define the services that are typically needed to address specific clinical cohorts of beneficiaries (those with similar risk-adjusted conditions), it is not possible to develop payment policies that encourage the delivery of reasonable and necessary services while discouraging the provision of services that do not produce a clinical benefit. Although there is widespread agreement that beneficiary condition and functional limitations are critical to developing and evaluating an alternative payment system for therapy services, a system for collecting such data uniformly does not exist. Currently diagnosis information is available from Medicare claims. However, we believe that the diagnosis on the claim is a poor predictor for the type and duration of therapy services required. Additional work is needed to develop an appropriate system for classifying clinical cohorts to determine therapy needs.

A 5-year CMS project titled ''Development of Outpatient Therapy Payment Alternatives'' (DOTPA) is expected to provide some of this information. The purpose of the DOTPA project is to identify a set of measures that we could collect routinely and reliably to support the development of payment alternatives to the therapy caps. Specifically, the measures being collected are assessed for administrative feasibility and usefulness in identifying beneficiary need for outpatient therapy services and the outcomes of those services. The data collection processes have just been completed and a final DOTPA report is expected in late CY 2013. In addition to developing alternatives to the therapy caps, the DOTPA project reflects our interest in

value-based purchasing by identifying components of value, namely, the beneficiary need and the effectiveness of therapy services. Although we expect DOTPA to provide meaningful data and practical information to assist in developing improved methods of paying for appropriate therapy services, it is unlikely that this one project alone will provide adequate information to implement a new payment system for therapy. This study combined with data from a wider group of Medicare beneficiaries would enhance our ability to develop alternative payment policy for outpatient therapy services.

(c) System Description and Requirements

(1) Overview

Section 3005(g) of MCTRJCA requires CMS to implement a claims-based data collection strategy on January 1, 2013 to gather information on beneficiary function and condition, therapy services furnished, and outcomes achieved. This information will be used in assisting us in reforming the Medicare payment system for outpatient therapy services. By collecting data on beneficiary function over an episode of therapy services, we hope to better understand the Medicare beneficiary population who uses therapy services, how their functional limitations change as a result of therapy services, and the relationship between beneficiary functional limitations and furnished therapy.

The long-term goal is to develop an improved payment system for Medicare therapy services. The desired payment system would pay appropriately and similarly for efficient and effective services furnished to beneficiaries with similar conditions and functional limitations that have potential to benefit from the services furnished. Importantly, such a system would not encourage the furnishing of medically unnecessary or excessive services. At this time, the data on Medicare beneficiaries' use and outcomes from therapy services from which to develop an improved system does not exist. This data collection effort is the first step towards collecting the data needed for this type of payment reform. Once the initial data have been collected and analyzed, we expect to identify gaps in information and determine what additional data would be needed to develop a new payment policy. Without a better understanding of the diversity of beneficiaries receiving therapy services and the variations in type and volume of treatments provided, we lack the information to develop a comprehensive strategy to map the way to an improved payment policy. While this claims-based data collection is only the first step in a long-term effort, it is an essential step.

In the CY 2013 proposed rule, we proposed to implement section 3005(g) of MCTRJCA by requiring that claims for therapy services include nonpayable G-codes and modifiers. Through the use of these codes and modifiers, we proposed to capture data on the beneficiary's functional limitations (a) At the outset of the therapy episode, (b) at specified points during treatment and (c) at discharge from the outpatient therapy episode of care. In addition, the therapist's projected goal for functional status at the end of treatment would be reported on the first claim for services and periodically throughout an episode of care.

Specifically, as proposed, G-codes would be used to identify what type of functional limitation is being reported and whether the report is on the current status, projected goal status or discharge status. Modifiers would indicate the severity/complexity of the functional limitation being tracked. The difference between the reported functional status at the start of therapy and projected goal status represents any progress the therapist anticipates the beneficiary would make during the course of treatment/episode of care. We proposed that these reporting requirements would apply to all therapy claims, including those for services above the therapy caps and those that include the KX modifier (described above).

By tracking any changes in functional limitations throughout the therapy episode of care and at discharge, we would have information about the therapy services furnished and the outcomes of such services. The ICD–9 diagnosis codes reported on the claim form would provide some information on the beneficiary's condition.

We proposed that these claims-based data collection requirements would apply to services furnished under the Medicare Part B outpatient therapy benefit and PT, OT, and SLP services under the Comprehensive Outpatient Rehabilitation Facilities (CORF) benefit. We also proposed to include therapy services furnished personally and ''incident to'' the services of physicians or nonphysician practitioners (NPPs). As we explained in the proposed rule, this broad applicability would include therapy services furnished in hospitals, critical access hospitals (CAHs), skilled nursing facilities (SNFs), CORFs, rehabilitation agencies, home health agencies (when the beneficiary is not under a home health plan of care), and in private offices of therapists, physicians and NPPs.

When used in this section ''therapists'' means all practitioners who furnish outpatient therapy services, including physical therapists, occupational therapists, and speech-language pathologists in private practice and those therapists who furnish services in the institutional settings, physicians and NPPs (including, physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), as applicable.) The term ''functional limitation'' generally encompasses both the terms ''activity limitations'' and ''participation restrictions'' as described by the International Classification of Functioning, Disability and Health (ICF). (For information on ICF, see *www.who.int/classifications/icf/en/* and for specific ICF nomenclature (including activity limitations and participation restrictions), see *http://apps.who.int/classifications/icfbrowser/*.

The CY 2013 proposal was based upon an option for claims-based data collection that was developed as part of the Short Term Alternatives for Therapy Services (STATS) project under a contract with CMS, which provided three options for alternatives to the therapy caps that could be considered in the short-term before completion of the DOTPA project. In developing options, the STATS project drew upon the analytical expertise of CMS contractors and the clinical expertise of various outpatient therapy stakeholders to consider policies and available claims data. The options developed were:

- Capturing additional clinical information regarding the severity and complexity of beneficiary functional impairments on therapy claims in order to facilitate medical review and at the same time gather data that would be useful in the long term to develop a better payment mechanism;
- Introducing additional claims edits regarding medical necessity to reduce overutilization; and
- Adopting a per-session bundled payment, the amount of which would vary based on beneficiary characteristics and the complexity of evaluation and treatment services furnished in a therapy session.

Although we did not propose to adopt any of these alternatives at that time, we discussed and solicited public comments on all aspects of these options during the CY 2011 rulemaking. (See 75 FR 40096 through 40100 and 73284 through 73293.) In developing the CY 2013 claims-based data collection proposal, we used the feedback received from the CY 2011 rulemaking.

We noted in the proposal that the proposed claims-based data collection system using G-codes and severity modifiers builds upon current Medicare requirements for therapy services. Section 410.61 requires that a therapy plan of care (POC) be established for every beneficiary receiving outpatient therapy services. This POC must include: the type, amount, frequency, and duration of services to be furnished to each beneficiary, the diagnosis and the anticipated goals. Section 410.105(c) contains similar requirements for services furnished in the CORF setting. We have long encouraged therapists, through our manual provisions, to express the POC-required goals for each beneficiary in functional terms and require that goals be based on measureable assessments or objective data and relate to identified functional impairments. See Pub 100–02, Chapter 15, Section 220.1.2. We also noted that the evaluation and the goals developed as part of the POC would be the foundation for the initial reporting under the proposed system.

The following is a summary of the comments we received regarding the general approach proposed in the CY 2013 PFS proposed rule to require nonpayable G-codes and modifiers on therapy claims to implement the new statutory requirement.

Comment: Most commenters supported a new payment system for therapy services and recognized that data would be a critical factor in the development of such a system. Others recognized that the statute required CMS to implement a claims-based data collection system and therefore addressed comments to the specific elements rather than the overall requirement. Many commenters expressed concerns that the data we would be collecting under the proposed system would not provide adequate data for us to develop a new payment system. Many commenters also expressed concern that the system would not provide the means for therapists to adequately convey why some beneficiaries needed more treatment. Toward this end, commenters suggested that we include a way to risk adjust the data or collect more beneficiary information. Some commenters suggested that we establish additional G-codes to report the beneficiary's complexity, such as whether their condition is of low, moderate, or high complexity. These G-codes would represent the multiple variables that affect a beneficiary's condition and response to therapy, such as age, comorbidities, prognosis, patient safety considerations, and current clinical presentation. One association indicated that it is working on an alternative payment system that will define and use three levels of complexity. Many commenters pointed out that the data we proposed to collect could only provide information on the progress an individual beneficiary made and was not valid for analyzing payment alternatives.

Response: We agree with commenters that the data collected under this system will not alone provide all the information that CMS needs to develop, analyze and implement an alternative payment system. We agree with the commenters that factors such as the patient's overall condition, including age, comorbidities, etc. are likely to affect the response to therapy; and we further agree that being able to analyze the data collected on such variables would enhance the usefulness of our data. Although we agree with the commenters' that it could be beneficial to include additional data elements to reflect the patient's condition and the complexity of the case, a meaningful system to use in classifying a beneficiary's complexity does not currently exist. As experience is gained with this new system, we expect that through future notice and comment rulemaking we will be able to enhance the system.

Comment: Many commenters commented on the administrative burden that therapists would incur if the proposed system was implemented. Some commented that the administrative burden would be particularly significant for physical therapists in private practice who often submit claims after each therapy visit. Commenters labeled the proposal ''improper,'' ''unreasonable,'' and ''overly burdensome.'' Other commenters indicated that the proposed process would not be burdensome stating that the functional assessment tools they use were ''perfectly suited to comply with CMS rule for data collection points, so we anticipate little or no burden in complying with the collection of function at intake, predicting discharge function at intake, during care and at discharge from care.'' In addition to the many commenters who noted the additional work that would be required to comply with this system, one commenter suggested that we also add a billable G-code to pay therapists for the additional work that this proposal would require.

Response: While we recognize that complying with these new reporting requirements will impose an additional burden on therapists, we believe that having available additional data on the therapy services furnished and the beneficiaries who receive them is critical to development of an alternative payment system for therapy services. Although we acknowledge that there would be work and some additional effort in complying with these reporting requirements, we believe that the additional burden is minimal. We designed our proposal to mesh closely with information that therapists already include in the medical record. The proposal would merely require that the information be translated into the new G-codes and modifiers, and included in additional lines on the same claims that would otherwise be submitted. We do not believe this reporting requirement would significantly increase the resources required to furnish therapy services.

Comment: A couple of commenters suggested that we abandon our G-code/modifier proposal and use diagnosis codes in its place. One recognized that CMS's assertion that diagnosis codes on the claims do not provide the data that we need was valid when only the principal diagnosis is used, but stated that if we relied upon principal and secondary diagnosis we could obtain the additional information regarding the patient's clinical condition and functional limitations. The commenter provided the example of when hemiparesis was coded as the secondary diagnosis. Some suggested that when the ICD–10 system is implemented the diagnosis codes would provide better information.

Response: We continue to believe that diagnosis codes, even when secondary diagnoses are included, do not provide the information on functional limitations that the statute requires us to collect. In the example the commenter provided, use of the diagnosis code ''hemiparesis,'' would only tell us that the beneficiary needs therapy due to a paralysis or weakness on one side of his or her body caused by a stroke or other brain trauma, but not the extent of the beneficiary's functional limitation. With regard to use of ICD–10, the statute requires us to implement a functional reporting system by January 1, 2013 so we cannot wait for ICD–10 system to implement the reporting requirements.

Comment: One commenter requested to be exempted from these reporting requirements because the organization furnishes such a small amount of Part B outpatient therapy services. Another noted that ''Given that this policy may affect HOPDs only for 3 months, CMS should consider ways to impose minimal administrative burden on HOPDs to implement this policy.'' One commenter sought assurance that CAHs

were included in this data collection effort.

Response: As we indicated in the proposed rule, our goal is to have data on the complete range of therapy services for which payment is made based on the PFS for use in assessing and developing potential alternative payment systems for those services. This is important since any new payment system would likely apply to all those therapy services that are currently paid at rates under the PFS. To meet this goal, we proposed that the reporting requirements apply to all providers and suppliers of outpatient therapy services and CORFs. We note that the proposed policy would apply to hospital outpatient department services, even if such services are not subject to the therapy caps after December 31, 2012, and to services furnished in CAHs. We are finalizing without change the proposed policy to apply the reporting requirements to hospitals, SNFs, rehabilitation agencies, CORFs, home health agencies (when the beneficiary is not under a home health plan of care) and private offices.

Comment: Several commenters raised concerns about a new payment system based upon the data collected without a standardized tool, stating that such data would not provide reliable information on which to develop an alternative payment system. Additionally, some commenters believed the invalid data would be used to create a payment system based upon functional limitations.

Response: At this time we are not making any changes in the existing payment methodology for therapy services, except that therapists will have to comply with the reporting requirements to receive payment for furnished therapy services. Therapists will continue to be paid in CY 2013 under the existing payment methodology, which includes the therapy caps. We will closely monitor and implement any enacted legislation that would amend the current statutory provisions, including any amendment to extend the therapy cap exceptions process. At this time we are broadly considering options for a revised payment system for therapy services and do not have any preconceived ideas as to what such a system would like or what it would be based upon. The purpose of the data collection proposal described in the CY 2013 PFS proposed rule is to meet the statutory requirement and begin to gather data that will be used, along with other data and information that we have, to develop and analyze potential alternative payment systems. It is likely that changes will be made in the data collected as we gain experience with this system. Therapists and others concerned with Medicare payment for therapy services should not draw conclusions about any future payment system for therapy services based upon the claims-based data that we proposed to collect. The claims-based data is only one set of information that will be used and it is only a beginning step in gathering the information that we would need to consider in developing a revised payment system for therapy services.

Comment: Some commenters suggested that the ''preamble language implies that improvement is a requirement for ongoing Medicare coverage.'' One commenter suggested that the preamble language ''implies that a measurable improvement in a beneficiary's functional limitation is required during an episode of therapy services.'' Others expressed concern that some beneficiaries, such as those with spinal cord injuries, will be denied coverage because they improve too slowly.

Response: We did not intend for the preamble language to raise concern about changing coverage conditions for beneficiaries who need therapy services. As noted above, the purpose of the claims-based data collection system is simply to gather data, and we did not propose, nor are we implementing, any changes to coverage or payment policy for therapy services other than to require that therapists comply with the reporting requirements to receive payment for therapy services they furnish. Under existing IOM requirements, therapists have to establish a long-term goal for beneficiaries receiving therapy. What is new under this system is that at the outset of treatment, the therapist will need to report on the claim the projected goal for treatment using modifiers that describe the percentage of impairment. For beneficiaries who are not expected to improve, such as those receiving maintenance therapy, the same modifier would be used for current status and for projected goal status. It is possible for some beneficiaries that while improvement is expected, it is expected to be limited, and thus it will also be reported using the same modifiers. To emphasize, the collection of these data elements will not affect a beneficiary's coverage of therapy services.

Comment: Some commenters expressed concerns about how this proposal would affect individuals suffering from lymphedema. Commenters stated that some clients experience both pain and swelling while others seem to have only swelling of a limb. Successful management of a beneficiary with lymphedema involves bandaging, compression and skin care instruction, manual lymph drainage, decongestive therapy, manual lymph drainage instruction, and exercise. These services take lots of valuable practitioner time to perform correctly as does instructing caregivers. While lymphedema impacts function to a point of mild to severe disability, many commenters told us that lymphedema severity/complexity is very difficult to quantify and show significant functional improvements in the lymphatic system when many of these improvements are in skin integrity, cellular health and lymphatic flow. Other commenters stated that the patient's functional limitations due to lymphedema (restricted motion and/or mobility) can range from profound to minimal. But all lymphedema patients, including those proficient in self-care who have minimal functional limitations, are at great risk for developing cellulitis or other major medical complications from sustained tissue congestion of the lymphatic system. With ongoing or periodic management, as appropriate, therapy services can successfully prevent these medical crises. Many commenters expressed concern that coverage for therapy services relating to lymphedema would be denied as a result of this proposal. Others questioned which functional limitation to use for lymphedema patients.

Response: As noted earlier, we did not propose to change coverage policy or to use the claims-based data reporting system to determine which beneficiaries are entitled to therapy services. Instead, our proposal would require those furnishing care to provide certain information about the beneficiary and his or her expected response to therapy. We are reiterating in this final rule with comment period that the proposed claims-based data collection system makes no changes in our therapy coverage policies.

With regard to how those treating beneficiaries should comply with the data collection system, we expect therapists to report the G-code for the functional limitation that most closely relates to the functional limitation being treated. As a result of comments on the proposed rule, we are clarifying in this final rule with comment period that if the therapy services being furnished are not intended to treat a functional limitation, the therapist should use the G-code for ''other'' and the modifier representing zero.

Comment: Several commenters suggested that significant education will

be required for therapists to comply with this required reporting.

Response: We are publishing in this final rule with comment period the claims-based reporting requirements that must be met in order to receive payment for therapy services. We will also use our usual methods for providing additional information, including revising relevant sections of the IOM, publishing Medicare Learning Network (MLN) Matters articles; presentations on Open Door Forums, and conducting National Provider Calls on the new requirements. We urge therapist to use these tools to assure that they have the information they need to comply with these new requirements.

(2) Nonpayable G-Codes on Beneficiary Functional Status

We proposed that therapists would report G-codes and modifiers on Medicare claims for outpatient therapy services. We discussed and sought comment on two types of G-codes in the proposed rule—generic and categorical. Table 19 shows the proposed generic G-codes and Table 20 shows the categorical codes discussed in the proposed rule.

TABLE 19—PROPOSED NONPAYABLE G-CODES FOR REPORTING FUNCTIONAL LIMITATIONS

Functional limitation for primary functional limitation:	
Primary Functional limitation, Current status at initial treatment/episode outset and at reporting intervals	GXXX1
Primary Functional limitation, Projected goal status	GXXX2
Primary Functional limitation, Status at therapy discharge or end of reporting	GXXX3
Functional limitation for a secondary functional limitation if one exists:	
Secondary Functional limitation, Current status at initial treatment/outset of therapy and at reporting intervals	GXXX4
Secondary Functional limitation, Projected goal status	GXXX5
Secondary Functional limitation, Status at therapy discharge or end of reporting	GXXX6
Provider attestation that functional reporting not required:	
Provider confirms functional reporting not required	GXXX7

The proposed G-codes differ from the three separate pairs of G-codes discussed in the CY 2011 PFS rulemaking. The CY 2011 discussion included these three pairs of G-codes, all of which reflect specific ICF terminology:

- Impairments of Body Functions and/or Impairments of Body Structures;
- Activity Limitations and Participation Restrictions; and
- Environmental Factors Barriers.

Each pair contained a G-code to represent the beneficiary's current functional status and another G-code to represent the beneficiary's projected goal status. Each claim would have required all three sets of G-codes. Like the G-codes we proposed for CY 2013, the G-codes discussed in the CY 2011 PFS rulemaking would have been used with modifiers to reflect the severity/complexity of each element.

In the CY 2013 PFS proposed rule, we indicated that we were not proposing to use these specific G-codes because we found them to be potentially redundant and confusing. Instead we chose to use G-codes to define ''functional limitations'' synonymously with the ICF terminology ''activity limitations and participation restrictions.'' We noted that requiring separate reporting on three elements would have imposed a greater burden on therapists without providing a meaningful benefit in the value of the data provided. We added that because environmental barriers as discussed in CY 2011 are contextual, we did not believe collecting information on them would contribute to developing an improved payment system.

To create the select categories of G-codes discussed in the proposed rule (See Table 20) we used the two most frequently reported functional limitations in the DOTPA project by each of the three therapy disciplines. We noted that should we decide to use a system with category-specific reporting, we would expect to develop specific nonpayable G-codes for select categories of functional limitations in the final rule. We explained that if one of the select categories of functional limitations describes the functional limitation being reported, that G-code set would be used to report the current, projected goal, and discharge status of the beneficiary. When reporting a functional limitation not described by one of categorical G-codes, one of the generic G-codes previously described would be used.

TABLE 20—SELECT CATEGORIES OF G-CODES DISCUSSED IN PROPOSED RULE

Walking & Moving Around	
Walking & moving around functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXXX8
Walking & moving around functional limitation, projected goal status, at initial therapy treatment/outset and at discharge from therapy	GXXX9
Walking & moving around functional limitation, discharge status, at discharge from therapy/end of reporting on limitation	GXX10
Changing & Maintaining Body Position	
Changing & maintaining body position functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXX11
Changing & maintaining body position functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy	GXX12
Changing & maintaining body position functional limitation, discharge status at discharge from therapy/end of reporting on limitation	GXX13
Carrying, Moving & Handling Objects	
Carrying, moving & handling objects functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXX14
Carrying, moving & handling objects functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy	GXX15

TABLE 20—SELECT CATEGORIES OF G-CODES DISCUSSED IN PROPOSED RULE—Continued

Carrying, moving & handling objects functional limitation, discharge status at discharge from therapy/end of reporting on limitation	GXX16
Self Care (washing oneself, toileting, dressing, eating, drinking)	
Self care functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXX17
Self care functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy	GXX18
Self care functional limitation, discharge status at discharge from therapy/end of reporting on limitation	GXX19
Communication: Reception (spoken, nonverbal, sign language, written)	
Communication: Reception functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXX20
Communication: Reception functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy	GXX21
Communication: Reception functional limitation, discharge status at discharge from therapy/end of reporting on limitation	GXX22
Communication: Expression (speaking, nonverbal, sign language, writing)	
Communication: Expression functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXX23
Communication: Expression functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy	GXX24
Communication: Expression functional limitation, discharge status at discharge from therapy/end of reporting on limitation	GXX25

We sought input from therapists on categories of functional limitations, such as those described in this section. We specifically requested comments regarding the following questions: Would data collected on categories of functional limitations provide more meaningful data on therapy services than that collected through use of the generic G-codes in our proposal? Should we choose to implement a system that is based on at least some select categories of functional limitation, which functional limitations should we collect data on in 2013? Is it more, less or the same burden to report on categories of functional limitations or generic ones? The categories of functional limitations described above are based on the ICF categories, but these ICF categories also have subcategories. Should we use subcategories for reporting? Are there specific conditions not covered by these ICF categories? Would we need to have G-codes for the same categories of secondary limitations? We sought public comment on whether these proposed G-codes allow adequate reporting on beneficiary's functional limitations. We also noted that we would particularly appreciate receiving specific suggestions for any missing elements.

The following is a summary of the comments we received on the G-codes, generic and categorical, whether these proposed G-codes allow adequate reporting on beneficiary's functional limitations, and specific suggestions for any missing elements.

Comment: Two commenters disagreed with our proposal to develop new G-codes and instead encouraged us to use the three pairs of G-codes (activities and participation restrictions, impairments to body functions/structures and environmental barriers) from the STATs project to report functional limitations. These commenters agreed that adding these domains might be more burdensome, but one commenter suggested that without these data elements we would likely miss integral beneficiary data in relation to health and wellness benefits, such as increased muscle function, improved quality of life, decreased depression, improved bowel/bladder function, improved respiratory function, improved autonomic function and improved circulation. Another commenter specifically agreed with our decision to use only the one ICF-defined G-code from the STATS for activity impairments and participation restrictions. They noted that it would be potentially redundant and confusing to adopt the two additional G-codes for body functions/structures and environmental barriers and noted that these other two categories would ''provide the agency with little meaningful data.'' One commenter suggested that if we adopted this additional reporting we could minimize the additional burden by eliminating goal reporting.

Response: We appreciate the views of these commenters about which ICF categories to capture in our G-code data collection. We continue to believe that the reporting of functional limitations will be less confusing and more defined with the G-codes as described in our proposal for activity impairments/participation restrictions. As we move forward with functional reporting in following years, we may revisit the addition of other categories.

Comment: Commenters had divergent views on the categorical and generic G-codes. Many found the proposed system complicated, burdensome and stated that it would not provide the data we sought. Some criticized the categorical codes as being too broadly defined and stated that this will lead to confusion as to what areas of impairment are being reported. For example, one commenter stated, ''The suggested categories are very broad and, in our view, will lead to confusion regarding which areas of impairment would be reported for certain therapy activities.'' One commenter opposed the use of generic G-codes saying that data from these codes would be ''useless.'' On the other hand, we received much support for the proposed G-codes. Many commenters supported the use of categorical G-codes codes saying their use will provide more useful information than the generic ones. One commenter stated, ''We believe having therapists report on these categories will provide CMS with more useful information than generic reporting on a functional limitation.'' Many favored use of the categorical G-codes in addition to using ''generic'' or ''other'' codes only for functional limitations that did not fit in one of the categorical ones. Several commenters gave us specific guidance, recommending that instead of the generic G-codes, we add an ''other'' G-code to the categorical codes for functional limitations that don't fit into one of the defined categories.

Response: Based upon the comments we received suggesting that we use the categorical codes, but include an ''other'' category to use when one of the categorical codes does not apply, we are modifying our proposal to adopt categorical G-codes to define functional limitations and including within the categorical G-codes ''other'' G-codes to use when one of the more specific categorical codes does not apply. In addition to this change, as discussed below, we are replacing the two SLP categorical codes with eight new ones to better reflect the diversity of services

furnished. Table 21 provides a complete list of the codes that will be available for reporting functional limitations. With regard to the commenters' concern that the categories are too broad and this will lead to confusion as to what is being reported, we acknowledge that the categories are broad, but disagree that the use of broad categories will result in confusion. Instead, we believe that the result will be the collection of data that includes information on broadly defined functional limitations. Without more specific input and greater support from the commenters, we do not believe we should create these in this final rule with comment period. Moreover, we believe it is important to gain experience with a limited number of codes in this new reporting system before we vastly expand the number of codes that are used. We sought comment on ways to better define the categories and where we received specific suggestions for additional G-codes that were sufficiently developed, such as those for SLP (explained below), we included them in our final set of G-codes. We anticipate that we will continue to refine the categories through future notice and comment rulemaking as we get more information and experience with this system.

Comment: Several commenters pointed out that there were many functional limitations for which there was not a categorical G-code. The American Speech-Language and Hearing Association pointed out the lack of appropriate SLP categories and suggested that we take advantage of the experience that has been gained through the use of its system for collecting data on functional limitations in this area. Specifically, they urged us to assign G-codes to the top seven reported functional communication measures used in National Outcomes Measurement System (NOMS). This commenter stated that, using this system, we would be able to collect ''consistent'' and ''meaningful'' ratings across all settings nationally.

Others told us that there were many conditions and situations that our system did not address and that some of these beneficiaries did not exhibit functional limitations that could be easily measured or reported. They cited, as examples, beneficiaries seen for lymphedema management, wound care, wheelchair assessment/fitting, cognitive impairments, and incontinence training.

Response: We agree with commenters that the G-codes discussed in the proposed rule did not go far enough in addressing SLP functional limitations. After consideration of the comments, we also agree that adoption of the most frequently used NOMS measures would be the best way to address this issue and would significantly improve our system in several ways. By using a system familiar to many speech-language pathologists, the quality of our data collection will be enhanced and the burden on those reporting will be less. We agree that it is reasonable to incorporate categories that are more specific, when appropriate, and note that this is an opportunity to align with existing measurement systems.

Accordingly, we are replacing the two of the categorical codes relating to SLP with seven categorical codes and one ''other'' code for SLP. (See Table 21.) The seven categorical codes mirror the seven most frequently reported NOMS categories and should be used when appropriate. For all other SLP treatments, the ''SLP Other'' category should be used.

For functional limitations not defined by the specific categorical codes and for therapy services that are not addressing a particular functional limitation; the ''other'' G-codes should be used. As we begin collecting data in this initial year, we will continue to assess the need for additional G-codes, refinement of existing ones, and examine ways to address those situations for which beneficiaries do not have functional limitations.

We have addressed in this final rule with comment period those areas for which we have adequate information to do so at this time and for which an additional burden will not be created. We will continue to refine this system through further notice and comment rulemaking in future years.

Comment: We received mixed feedback in response to our request for comment regarding the use of the ICF subcategories. Some commenters noted that adding more subcategories would result in too many codes and only add to the confusion. At least one other commenter supported subcategory reporting, but did not suggest which subcategories we should use.

Response: Given the comments received, we will not be implementing reporting by subcategories at this time. Once the system is operational, we will reassess whether subcategory reporting is necessary to provide the data that we need.

Comment: Some commenters interpreted our proposal to limit each therapy discipline to using only the two codes that represented the top two reported functional limitations for that discipline and suggested that we allow therapists to use any appropriate functional limitation.

Response: We agree with commenters that therapists should be able to use any appropriate functional limitation. In the proposed rule, we indicated that we developed the 6 categorical codes to correspond with the two most commonly reported functional limitations for each of the three therapy disciplines. However, this was only a way of identifying the functional limitations for which we needed codes. To be clear, therapists are to use the most appropriate categorical G-code that describes the functional limitation that is the primary reason for treatment without restriction by discipline.

Comment: A few commenters urged us to clarify that therapists using Patient Inquiry by Focus on Therapeutic Outcomes, Inc (FOTO), or another measurement system that provides a composite functional status score, did not need to report on secondary limitations.

Response: In assessing this comment, we recognized the need to clarify how composite functional scores should be reported. We are clarifying that a composite score should be reported using G8990 (Other physical or occupational primary functional limitation, current status, at therapy episode outset and at reporting intervals), G8991(Other physical or occupational primary functional limitation, projected goal status, at therapy episode outset, at reporting intervals, and at discharge or to end reporting) and G8992 (Other physical or occupational primary functional limitation, discharge status, at discharge from therapy or to end reporting). Should there be the occasion to report on a second condition after the reporting on the first had ended, the therapist would use the G-code set for ''other subsequent'' functional limitation, G8993–G8896.

(3) Number of Functional Limitations on Which Reporting Occurs

We proposed that, using a set of G-codes with appropriate modifiers, the therapist would report the beneficiary's primary functional limitation defined as the most clinically relevant functional limitation at the time of the initial therapy evaluation and the establishment of the POC. The projected goal would also be reported at this time. At specified intervals during treatment, claims would also include the current functional status and the goal functional status, which would not typically change during therapy, except as described below. On the final claim for an episode of care, the therapist would report the status at this time for this functional limitation and the goal status.

Early results from the DOTPA project suggest that most beneficiaries have more than one functional limitation at treatment outset. In fact, only 21 percent of the DOTPA assessments reported just one functional limitation. Slightly more than half (54 percent) reported two, three or four functional limitations.

To the extent that the DOTPA finding is typical, the therapist may need to make a determination as to which functional limitation is primary for reporting purposes. In cases where this is unclear, the therapist may choose the functional limitation that is most clinically relevant to a successful outcome for the beneficiary, the one that would yield the quickest and/or greatest mobility, or the one that is the greatest priority for the beneficiary. In all cases, this primary functional limitation should reflect the predominant limitation that the furnished therapy services are intended to address.

We sought comment on specific issues regarding reporting data on a secondary limitation. Specifically, we requested comments regarding whether reporting on secondary functional limitations should be required or optional.

The following is a summary of the comments we received on the percentage of Medicare therapy beneficiaries with more than one functional limitation at the outset of therapy and whether reporting on secondary functional limitations should be required or optional.

Comment: The responses on the number of functional limitations being treated showed a wide variation. One commenter treating beneficiaries with spinal cord injuries indicated that 100 percent had more than one functional limitation, with an average of 10 functional limitations. Another respondent told us that 50 percent of SLP patients have two or more functional limitations. Another respondent indicated that nearly 98 percent of patients seen by therapists using FOTO were surveyed for only one condition. Most commenters recommended that therapists be required to report only one functional limitation, especially as we are just beginning to require functional reporting. The commenters stated that it would be burdensome and would pose clinical challenges to require reporting both a primary and secondary functional limitation. Others suggested that it would be costly, time intensive and burdensome to report numerous secondary functional limitations. Some stated that reporting on only one functional limitation would not capture sufficient information since treatment of multiple functional limitations is interrelated and treatment for these occurs simultaneously, not sequentially. Some commenters suggested allowing the optional reporting of a second or third functional limitation. Some commenters questioned how functional reporting would be handled when the beneficiary was being treated by more than one discipline or when a substitute therapist treats a beneficiary.

Response: In response to comments, we have decided to limit reporting to one functional limitation at this time. Recognizing that therapists treat the patient as a whole and work on more than one functional limitation at a time, we believe that limiting reporting in this way will make it less burdensome in the situations involving more than one functional limitation. Although many commenters favored the option of reporting on additional functional limitations when appropriate, we believe that allowing additional optional reporting would not produce consistent or useful data on beneficiaries who have more than one functional limitation that is being treated, and could potentially complicate the use of the data we collect for the development of future therapy payment policy. As we seek to improve reporting in future years, we may reconsider whether to permit or require reporting on additional functional limitations. We note that this is a new reporting system designed to gather data on the changes in beneficiary function throughout an episode of care. We are not expecting therapists to change the way they treat patients because of our reporting requirements.

We also explained that in situations where treatment continues after the treatment goal is achieved and reporting ended on the primary functional limitation, reporting will be required for another functional limitation. Thus, reporting on more than one functional limitation may be required for some patients, but not simultaneously. Instead, once reporting on the primary functional limitation is complete, the therapist will begin reporting on a subsequent functional limitation using another set of G-codes. If this additional functional limitation is not described by one of the specific categorical codes, one of the three ''other'' codes should be used depending on the circumstances.

In response to the comments, we are making several modifications in the G-codes that we proposed, as noted in the responses to comments above. To summarize, the G-codes, and their long descriptors, that will be used for reporting functional limitations of beneficiaries are listed in Table 21. There are 11 G-codes that describe categorical functional limitation, including seven for SLP services, and three more general G-codes for functional limitations that do not fit within one of the 11 categories. The general categorical codes would be used when none of the specific categories apply or when an assessment tool is used that yields a composite score that combines several or many functional measures, such as is done with the FOTO Patient Inquiry tool, for example. Two of these general G-code sets are to be used for ''other'' PT and OT services and one for ''other'' SLP services. In addition, we deleted the requirement to report a G-code to signal that no reporting was required and thus deleted the G-code that would have been used for this. (For discussion about the comments on this G-code and our decision to remove this reporting requirement, see section II.F.2.(b).(6).) Therapists would use the code that best describes the functional limitation that is primary to the therapy plan of care.

TABLE 21—G-CODES FOR CLAIMS-BASED FUNCTIONAL REPORTING FOR CY 2013

Mobility: Walking & Moving Around	
G8978	Mobility: walking & moving around functional limitation, current status, at therapy episode outset and at reporting intervals.
G8979	Mobility: walking & moving around functional limitation, projected goal status, at therapy episode outset, at reporting intervals, and at discharge or to end reporting.
G8980	Mobility: walking & moving around functional limitation, discharge status, at discharge from therapy or to end reporting.
Changing & Maintaining Body Position	
G8981	Changing & maintaining body position functional limitation, current status, at therapy episode outset and at reporting intervals.

TABLE 21—G-CODES FOR CLAIMS-BASED FUNCTIONAL REPORTING FOR CY 2013—Continued

G8982	Changing & maintaining body position functional limitation, projected goal status, at therapy episode outset, at reporting intervals, and at discharge or to end reporting.
G8983	Changing & maintaining body position functional limitation, discharge status, at discharge from therapy or to end reporting.
	Carrying, Moving & Handling Objects
G8984	Carrying, moving & handling objects functional limitation, current status, at therapy episode outset and at reporting intervals.
G8985	Carrying, moving & handling objects functional limitation, projected goal status, at therapy episode outset, at reporting intervals, and at discharge or to end reporting.
G8986	Carrying, moving & handling objects functional limitation, discharge status, at discharge from therapy or to end reporting.
	Self Care
G8987	Self care functional limitation, current status, at therapy episode outset and at reporting intervals.
G8988	Self care functional limitation, projected goal status, at therapy episode outset, at reporting intervals, and at discharge or to end reporting.
G8989	Self care functional limitation, discharge status, at discharge from therapy or to end reporting.
	Other PT/OT Primary Functional Limitation
G8990	Other physical or occupational primary functional limitation, current status, at therapy episode outset and at reporting intervals.
G8991	Other physical or occupational primary functional limitation, projected goal status, at therapy episode outset, at reporting intervals, and at discharge or to end reporting.
G8992	Other physical or occupational primary functional limitation, discharge status, at discharge from therapy or to end reporting.
	Other PT/OT Subsequent Functional Limitation
G8993	Other physical or occupational subsequent functional limitation, current status, at therapy episode outset and at reporting intervals.
G8994	Other physical or occupational subsequent functional limitation, projected goal status, at therapy episode outset, at reporting intervals, and at discharge or to end reporting.
G8995	Other physical or occupational subsequent functional limitation, discharge status, at discharge from therapy or to end reporting.
	Swallowing
G8996	Swallowing functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G8997	Swallowing functional limitation, projected goal status, at initial therapy treatment/outset and at discharge from therapy.
G8998	Swallowing functional limitation, discharge status, at discharge from therapy/end of reporting on limitation.
	Motor Speech
G8999	Motor speech functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G9157	Motor speech functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy.
G9158	Motor speech functional limitation, discharge status at discharge from therapy/end of reporting on limitation.
	Spoken Language Comprehension
G9159	Spoken language comprehension functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G9160	Spoken language comprehension functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy.
G9161	Spoken language comprehension functional limitation, discharge status at discharge from therapy/end of reporting on limitation.
	Spoken Language Expression
G9162	Spoken language expression functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G9163	Spoken language expression functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy.
G9164	Spoken language expression functional limitation, discharge status at discharge from therapy/end of reporting on limitation.
	Attention
G9165	Attention functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G9166	Attention functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy.
G9167	Attention functional limitation, discharge status at discharge from therapy/end of reporting on limitation.
	Memory
G9168	Memory functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G9169	Memory functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy.
G9170	Memory functional limitation, discharge status at discharge from therapy/end of reporting on limitation.

TABLE 21—G-CODES FOR CLAIMS-BASED FUNCTIONAL REPORTING FOR CY 2013—Continued

Voice	
G9171	Voice functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G9172	Voice functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy.
G9173	Voice functional limitation, discharge status at discharge from therapy/end of reporting on limitation.
Other SLP Functional Limitation	
G9174	Other speech language pathology functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G9175	Other speech language pathology functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy.
G9176	Other speech language pathology functional limitation, discharge status at discharge from therapy/end of reporting on limitation.

(4) Severity/Complexity Modifiers

We proposed that for each functional G-code used on a claim, a modifier would be required to report the severity/complexity for that functional limitation. We proposed to adopt a 12-point scale to report the severity or complexity of the functional limitation involved. The proposed modifiers are listed in Table 22.

TABLE 22—PROPOSED MODIFIERS

Modifier	Impairment limitation restriction difficulty
XA	0%.
XB	Between 1–9%.
XC	Between 10–19%.
XD	Between 20–29%.
XE	Between 30–39%.
XF	Between 40–49%.
XG	Between 50–59%.
XH	Between 60–69%.
XI	Between 70–79%.
XJ	Between 80–89%.
XK	Between 90–99%.
XL	100%.

We noted that there are many valid and reliable measurement and assessment tools that therapists use to inform their clinical decision-making and to quantify functional limitations, including the four assessment tools we discussed in CY 2011 PFS rulemaking that produce functional scores—namely, the Activity Measure—Post Acute Care (AM–PAC) tool, the FOTO Patient Inquiry, OPTIMAL, and NOMS. We list these four tools as recommended for use by therapists, though not required, in the outpatient therapy IOM provision of the Benefits Policy Manual, Chapter 15, Section 220.3C ''*Documentation Requirements for Therapy Services.''* We suggested that the scores from these and other measurement tools already in use by therapists that produce numerical or percentage scores be mapped or crosswalked to the proposed 12-point severity modifier scale.

In assessing the ability of therapists to provide the required severity information regardless of what assessment tool or combination of tools they use, if any, we considered the comments received on the CY 2011 PFS proposed rule discussion. These indicated that we needed greater granularity in our severity scale so that the changes in functional limitation over the course of therapy could be more accurately reflected. Specifically, most commenters on the CY 2011 proposed rule favored the 7-point scale over the 5-point ICF-based scale. They indicated that they preferred a scale with more severity levels and equal increments since it would allow the therapist to document smaller changes that many therapy beneficiaries make towards their goals.

Believing that neither the 5- or 7-point scales would be adequate for this reporting system, we developed and proposed a 12-point scale that we believed was an enhancement over the 7-point scale. We thought it addressed concerns that those commenting on the CY 2011 options had raised regarding the 7-point scale. We thought that a more sensitive rating scale (one with more increments) had the advantage of demonstrating the progress of beneficiaries with conditions that improve slowly, such as those recovering from strokes or with spinal cord injuries. In addition, we believed that the proposed scale's 10-percentage point increments would make it easier for therapists to convert composite and overall scores from assessment instruments or other measurement tools to this scale.

The following is a summary of the comments we received regarding our proposal for a 12-point scale to capture the severity/complexity of beneficiaries' functional limitations.

Comment: Several commenters stated that not all tests and measurement tools that therapists use could be easily crosswalked to any single numerical scale, stating that, for example, some tests and measures of functional limitations use ordinal scales. Further, the scores from some tests that are not linear or proportional to each other are not easily translatable to the 12-point scale. Some commenters pointed out the problems of developing a single score when more than one tool is used. Some commenters noted that there are a wide variety of therapy measurement tools that are used to inform clinical decision making and these are not measures that typically produce a functional assessment. Further, these commenters told us that combining the results of multiple measures make it extremely difficult to quantify beneficiary function and, as such, said it will be very difficult to crosswalk this type of information to a severity scale. And, many of these commenters expressed concerns about how therapist will implement the use of our severity/complexity modifier scale; they noted that much education is needed for therapists to understand the selection of a severity modifier. One commenter questioned whether aggregated subjective and objective data would be valid or usable by CMS.

Response: It is essential that the data reported on functional limitations be grouped using the same numeric scale. Moreover, we believe that is easier for those reporting data on functional limitations to use ranges of percentages rather than the absolute values. We acknowledge that therapists will incur some challenges when initially adopting our system as they learn how to translate the information obtained through various tests and measures to a particular modifier scale. However, as therapists gain experience in doing so, we anticipate that these translations will become easier and a normal part of their evaluative and treatment processes. Moreover, we are hopeful that forthcoming modifications from tool sponsors or others will make it easier for therapists to report the functional

limitations measured by these tools, such as modifying the tool so the results match the Medicare severity/complexity scale or issuing instructions or guidance on translating the results to the Medicare severity/complexity scale. We also expect that some translation tools are likely to become available. We are hopeful that forthcoming guidance and translation tools from tool sponsors and others will clarify some of translation questions therapists have regarding the Medicare severity scale. Given that it is essential for our purposes to have a severity/complexity scale, we are adopting one in this final rule. With regard to education, CMS will make information about the severity/complexity scale, as well as other aspects of our new system, widely available to therapists. It will be incumbent upon individual therapists to learn how to translate the score from a singular assessment tool or the combined results from multiple tests/measures along with other information regarding their patient's functional limitation to the Medicare scale. Finally, we acknowledge that a system that combines objective and subjective data is not ideal. However, at this time it appears that there is not an alternative. We will continue to refine and improve this system.

Comment: Some commenters offered alternative suggestions to the use of a severity/complexity scale. Several commenters suggested that we use the secondary diagnoses on claims instead. Others suggested capturing the medical complexity of a beneficiary using other indicators, such as E/M codes or co-morbidities.

Response: We appreciate these suggestions. While we are able to collect secondary diagnosis data from claims, we know from prior studies that diagnoses alone cannot predict the amount of therapy services needed. We do not believe that diagnoses and comorbidities measure functional limitations, which the statute requires us to collect. Nor do we believe using existing or therapy-specific E/M codes would provide the data on functional limitations that we are seeking to collect. We do, however, believe that these elements may provide additional data that could contribute to our analysis of payment alternatives. As we consider refinements to the claims-based data collection system in future years we will consider these additional data elements.

Comment: Commenters had differing views on the use of the proposed 12-point scale to convey the severity of the beneficiary's functional limitations. Those supporting the use of the proposed 12-point scale stated that it was more sensitive and so better reflected change in a beneficiary's functional limitation. For example, commenters using FOTO said that they would not have problems adopting our proposed 12-point scale because they receive a composite score from FOTO, based on the patient's functional survey results, which can be easily mapped as a percentage of overall beneficiary function. Other commenters suggested that the 12-point scale we proposed was too complicated and had too many levels. Some of these commenters also stated that therapists were not familiar with such a scale. Several commenters believed that we should modify the 12-point scale to a 10-point one by eliminating the separate modifiers for zero and 100 percent because they believed it would be more recognizable and easier for therapists to use. Many suggested that we use the 7-point scale discussed in the CY 2011 rulemaking. A couple of these commenters thought that this 7-point scale was a valid and reliable one. Another commenter added that a 7-point scale is used by many outcome tools, such as NOMS, although no other examples of a tool using a 7-point scale were provided. One commenter was opposed to a severity/complexity scale but suggested that if one was used, it should be a 5- or 7-point scale.

Response: After reviewing the comments, it is clear to us that, given the diversity of views among therapy professionals, the range in functional limitations being measured, the variability of beneficiary conditions being treated and the plethora of assessment tools and instruments being used, the translation of functional information to any scale used is likely to require adjustments by some therapists. Although we proposed a 12-point scale as we thought it would be easier to use and provided more sensitivity, a majority of commenters favored the 7-point scale over the 12-point scale. After consideration of the many comments on the use of a 12-point scale, we have determined that a 7-point scale as preferred by commenters will provide appropriate data for our analysis. Accordingly, are finalizing the 7-point scale in Table 23.

Comment: Some commenters read our proposal to require that therapists use one of the IOM-recommended assessment tools, and thought that we should allow therapists to assign a severity/complexity modifier using their clinical judgment when a functional assessment tool is not used. Other commenters noted that physical and occupational therapists typically use multiple measurement tools during the evaluative process to inform clinical decision making; and, that clinical judgment is needed to combine these results to determine a functional limitation percentage. One commenter pointed out that the IOM outpatient coverage guidelines recommend, but do not mandate, the use of standardized measurement instruments and sought guidance as to how the modifier scale would apply to a therapist who satisfies documentation guidelines but does not use a standardized measurement instrument that produces a global functional score.

Response: We appreciate commenters' concerns that our proposed policy would require therapists to use a functional assessment tool to determine the overall degree of functional impairment. This was not our intent. However, when one of the four functional assessment instruments is not utilized, we require as part of our IOM *Documentation Guidelines,* that the therapist documents using objective measures the beneficiary's physical functioning. We are also aware that use of one of the four functional instruments is not widespread; and that physical and occupational therapists typically use multiple objective tests and measures to establish and compare a beneficiary's physical function and progress throughout the therapy episode. As such, we recognize that a therapist's judgment is critical in determining how to best measure their patient's functional impairment and how to assimilate the various necessary objective findings to ascertain a certain percentage of function that can be translated to the Medicare severity scale. Our requirements for documenting the beneficiary's functional status were established prior to this data collection effort, and the primary purpose for measuring functional impairment continues to aid the therapist in furnishing therapy services. Our data collection system is designed to collect data that is developed in the evaluative process and assessed throughout the course of treatment, not to prescribe how or what measures therapists use to assess functional impairment or deliver services. Accordingly, it is acceptable for therapists to use their professional judgment in the selection of the appropriate modifier. Our IOM provisions already assert that when assessing the level of functional impairment, the therapist uses his/her professional judgments in addition to the objective measures and accepted methodologies that are recognized in the

therapy community and in professional practice guidelines.

Because there will be many cases for which one single functional measurement tool is not available or clinically inappropriate, therapists can use their clinical judgment in the assignment of the appropriate modifier. Therapists will need to document in the medical record how they made the modifier selection so that the same process can be followed at succeeding assessment intervals.

Comment: Many commenters evaluated our proposed 12-point scale as if it was itself to be used as an assessment tool, rather than simply a scale to report results of assessments. Some of these commenters also warned us that the 12-point scale could not give us valid and reliable data to use as an alternative payment system for therapy services unless a single assessment tool were used.

Response: We appreciate the views expressed by the many commenters. However, the 12-point scale was not intended to be used as an assessment tool. Rather, it was intended to be used to express the beneficiary's functional limitation in terms of a percentage of 100 total points so that there is a uniform scale for the degree of functional limitation. In other words, the scale that is used to report the degree of impairment would not affect the validity of the data. The reported data are as valid and reliable as the assessment tool or instrument (at times in combination with the therapist's judgment) that was used to develop the score. We also realize that there are limitations to the data that we will collect, in part because it is not all derived from one consistent, assessment tool.

Comment: Commenters noted that pain is a clinical complexity that is factored in when the beneficiary and therapist plan the course of treatment, but is not factored in to the proposed scale.

Response: We believe that the commenter meant that pain is a definite limiter of function and is difficult to measure and hard to quantify. However, we believe that pain and the functional limitations that it engenders can be captured by our severity scale. There are many valid and reliable measures that a therapist can use to quantify the functional limitations of painful conditions.

In response to the comments, we are adopting the following 7-point severity/complexity scale to report the severity of the beneficiary's functional impairment, which is based upon the scale developed as part of the STATs project.

TABLE 23—SEVERITY/COMPLEXITY MODIFIERS FOR CY 2013

Modifier	Impairment limitation restriction
CH	0 percent impaired, limited or restricted.
CI	At least 1 percent but less than 20 percent impaired, limited or restricted.
CJ	At least 20 percent but less than 40 percent impaired, limited or restricted.
CK	At least 40 percent but less than 60 percent impaired, limited or restricted.
CL	At least 60 percent but less than 80 percent impaired, limited or restricted.
CM	At least 80 percent but less than 100 percent impaired, limited or restricted.
CN	100 percent impaired, limited or restricted.

(4) Assessment Tools

In the proposed rule we noted that therapists frequently use assessment tools to quantify beneficiary function. FOTO and NOMS are two such assessment tools in the public domain that can be used to determine a score for an assessment of beneficiary function. Therapists could use the score produced by such instruments to select the appropriate modifier for reporting the beneficiary's functional status. Although we recommend the use of four of these functional assessment instruments to determine beneficiary functional limitation in the IOM, we did not propose to require the use of a particular functional assessment tool to determine the severity/complexity modifier. We explained our reasons for not doing so in the proposed rule saying ''Some tools are proprietary, and others in the public domain cannot be modified to explicitly address this data collection project. Further, this data collection effort spans several therapy disciplines. Requiring a specific instrument could create burdens for therapists that would have to be considered in light of any potential improvement in data accuracy, consistency and appropriateness that such an instrument would generate.'' We noted that we might reconsider this decision once we have more experience with claims-based data collection on beneficiary function associated with furnished therapy services. We sought public comment on the use of assessment tools. In particular, we were interested in feedback regarding the benefits and burdens associated with use of a specific tool to assess beneficiary functional limitations. We requested that those favoring a requirement to use a specific tool provide information on the preferred tool and describe why the tool is preferred.

The following is a summary of the comments we received regarding the use of assessment tools and the benefits and burdens associated with use of a specific tool to assess beneficiary functional limitations.

Comment: Many commenters appreciated that we recognized the need to use consistent and objective measurement tools to quantify beneficiary function. All commenters who addressed assessment tools agreed that there is not currently a single assessment tool that would meet the diverse needs of beneficiaries receiving therapy services, and most did not recommend requiring the use of a single tool. However, many commenters stated we would be ineffective in reaching our data collection goals without prescribing some rules about assessing function; and thus suggested alternatives due to concerns of consistency and validity of the data. MedPAC noted that collecting data without a tool ''would generate large amounts of data, and not provide clear information on the patients' limitations or functional status.'' MedPAC elaborated that variations among the assessment methods used by therapists ''would potentially impede the utility of such data for policymakers.''

Commenters found the following potential drawbacks to our proposal to allow therapists to choose the assessment tool(s) (or use their professional judgment) to determine the complexity/severity modifier. Commenters stated that the current proposal would collect individual level data that is not comparable among groups of beneficiaries or providers. Commenters also stated that gathering data on beneficiary condition, functional limitation, and progression necessitates the use of one standardized collection tool by all therapists. One commenter revealed that the same beneficiary could obtain widely distinct modifier scores depending on the tool used. Further, a commenter acknowledged that there are over 400 different measurement tools used by physical therapists, many of which only measure one domain of function. Additionally, another commenter urged us to provide more instruction on how each tool interfaces with the complexity/severity scale and provide crosswalks and guidance for each tool to promote consistency in the data collected.

Commenters suggested the following alternatives to our proposal to address the potential drawbacks they identified. Commenters supported endorsing a small number of standardized tools with proven validity, reliability, and responsiveness that would be distinct for each therapy discipline. The American Speech-Language and Hearing Association (ASHA) urged we adopt NOMS and a 7-point severity scale specifically for SLP to recognize the distinctiveness of the discipline and record meaningful outcomes for SLP beneficiaries. Many commenters supported the use of FOTO stating that it measures a broad scope of conditions reliably, results in a composite score, and creates little undue burden to report. Those commenters also stated that FOTO is already the tool of choice for their respective providers.

Two commenters suggested developing a list of approved tools for specific beneficiary populations and settings. Another commenter suggested assigning G-codes to specific assessment tools so that the data could be compared. As a future alternative, a few commenters proposed developing core items that could be used in any tool to standardize data collection. MedPAC suggested that ''CMS consider developing an instrument that collects the necessary information that would allow Medicare to categorize beneficiaries by condition and severity in order to pay appropriately'' and pointed to the ''Reason for Therapy'' form used in the DOTPA study as a starting point, noting that it is ''concise, easy to assess and document for clinicians, and collects information on function and limitations across three therapy disciplines.''

Response: We continue to recommend the use of four functional assessment tools to determine beneficiaries' functional limitations. In addition, when these tools are not used, we require the use of objective measures to document the functional status of beneficiaries. We continue to believe that no one tool currently meets the needs of all three therapy disciplines; and, therefore, we are not requiring the use of any one specific assessment tool, or even the use of any assessment tool. We acknowledge that because of the use of the variety and kinds of assessment tools and other measurement instruments, including the use of a therapist's professional judgment, the value of the data we collect under this system will have limitations. However, we believe that the data we gather will assist us in taking a first step towards an improved payment system.

We appreciate the comments providing information on the benefits of using specific tools, such as NOMS and FOTO. However, at this time we do not believe that they are sufficiently widely used to require the use of one of these tools. In this final rule with comment period, we are not requiring the use of a specific assessment tool. We are continuing to encourage, but not require, the use of assessment tools in the IOM.

We did, however, adopt G-codes and a modifier scale for SLP that are consistent with NOMS so it is possible to move to a standardized tool for SLP in the future. We will consider the possibility using coding to identify the specific functional assessment tool used in subsequent refinements. As noted above, therapists can also use their professional judgment in determining the percentage of functional limitations in conjunction with objective data from evaluations and assessments and the subjective reports from beneficiaries.

(5) Reporting Projected Goal Status

We proposed that the therapist's projected goal for the beneficiary's functional status at the end of treatment would be reported on the first claim for services, periodically throughout an episode of care, and at discharge from therapy.

The following is a summary of the comments regarding goal reporting.

Comment: Of those commenting on goal status, most objected to the collection of goal data, particularly during the first year of data collection. Commenters noted that reporting on goals was not specified as part of the claims-based data collection effort required by MCTRJCA. Some stated that it would be a significant practice change to report goal data, involving changes to medical documentation, electronic health records, and billing processes. Commenters stated the identification and reporting of goals raised several clinical issues, such as the variability in goals among therapists, the need to change goals over the course of treatment, and the fact that therapists often set several goals (for example, short and long-term goals) for each beneficiary. Others noted that using goal data to classify a group of beneficiaries would be flawed because therapists create goals specific to the individual. One commenter noted that if goals influence payment, therapists could set the goal low or high to induce ongoing therapy and therefore the data would not be useful. As a result of these factors, many commenters believed data reporting on therapy goals would not provide reliable and useful information. In addition, a number of commenters stated that the proposal did not clearly express the intent of collecting goal data and many commenters expressed concerns about how we would use this data. Some commenters suggested that we clarify that the functional status data would be used only to track a beneficiary's progression rather than for any other purposes, such as making comparisons across beneficiaries, therapists, or settings. Several commenters expressed concern that the reporting of goals implied an improvement standard and that care would be denied to beneficiaries who improved slowly or not at all. Alternatively, one commenter supported our proposal for reporting of a projected goal, as well as periodic updates of the beneficiary status in the context of that goal.

Response: We understand the commenters' concerns about the complexity and intricacies of goal reporting. However, we currently require in the Benefit Policy Manual (Chapter 15, section 220.1.2) that long-term treatment goals be developed for the entire episode of care. Further, we specify that the projected goals should be measurable and pertain to identified functional limitations, and that these goals also need to be documented in the medical record. Since many of these goal requirements already exist, the additional work imposed by this requirement would be for the therapist to establish the percentage of functional limitation for projected for this goal at the end of the therapy episode and translate the goal to the G-code/modifier scale. We understand that the claims-based reporting is a change for therapists; however, these adjustments in operations will yield meaningful information on beneficiary functional status. We appreciate the recommendation to delay goal reporting for a year, but we believe that it is important to include goal data to gather a complete description of a beneficiary's functional status.

At this time, we intend to use the projected goal to have an understanding of therapists' ability to project the likely progress a beneficiary will make. We ultimately may employ these data to help us develop proposals to improve payment for therapy services, but do not anticipate using the goal data for purposes of payment or coverage decisions. In cases where the therapist does not expect improvement, such as for those individuals receiving maintenance therapy, the reported projected goal status will be the same as current status. We appreciate that commenters raised concerns about

potential ambiguity of the description of the proposal on progress and outcomes but, given as we have clarified in this final rule with comment period, goal reporting does not establish an improvement standard. In fact, it allows the therapist to state at the outset the expectations. We understand there will be wide variability in goals. Since these goals are used in beneficiary treatment, as well as for reporting, we do not expect therapists to establish goals purely to make themselves look better. Recognizing the limitations of the collected goal data, we still believe it will be useful to us. Therefore, we are finalizing our requirement for reporting of goal G-codes on the claims form along with the related severity modifier for that goal.

(6) Reporting Frequency

We proposed to require claims-based reporting in conjunction with the initial service at the outset of a therapy episode, at established intervals during treatment, and at discharge. As proposed, the number of G-codes required on a particular claim would have varied from one to four, depending on the circumstances. We provided the following (Table 24) graphic example of which codes would have been used for periodic reporting. This example represents a therapy episode of care occurring over an extended period, such as might be typical for a beneficiary receiving therapy for the late effects of a stroke. We chose to use an example with a much higher than average number of treatment days in order to show a greater variety of reporting scenarios.

TABLE 24: Example of Proposed Reporting

	Evaluation/Treatment Day 1, Begin Reporting Period #1	End Reporting Period #1	Begin Reporting Period #2	Claim for treatment days 5 and 6 in Period #2	End Reporting Period #2	Begin Reporting Period #3	Discharge/End of reporting on Primary Functional Limitation	End Reporting Period #3
Primary Function Status								
GXXX1 – Current	X	X	X		X	X		
GXXX2 – Goal	X		X			X	X	
GXXX3 – Discharge							X	
Secondary Function								
GXXX4 – Current			X		X	X		X
GXXX5 – Goal			X			X		
GXXX6 – Discharge								
No Functional Reporting Required								
GXXXX7				X				

• *Outset.* As proposed, the first reporting of G-codes and modifiers would occur when the outpatient therapy episode of care begins. This would typically be the date of service when the therapist furnishes the evaluation and develops the required plan of care (POC) for the beneficiary. At the outset, the therapist would use the G-codes and modifiers to report a current status and a projected goal for the primary functional limitation. We indicated in the proposal that if a secondary functional limitation would need to be reported, the same information would be reported using G-codes and associated modifiers for the secondary functional limitation.

The following is a summary of comments on the frequency of reporting at the outset.

Comment: All commenters that addressed frequency of reporting agreed that reporting should occur at the outset of the therapy episode of care. Although commenters agreed with reporting at the outset, many recommended removing the requirement to report the projected goal status. (Comments on reporting projected goal status are discussed above.)

Response: We are finalizing the requirement to report current status and projected goal status at the outset of therapy.

• *Every 10 Treatment Days or 30 Calendar Days, Whichever Is Less.* We proposed to require reporting once every 10 treatment days or at least once during each 30 calendar days, whichever time period is shorter. As we explained in the proposed rule, the first treatment day for purposes of reporting would be the day that the initial visit takes place. The date the episode of care begins, typically at the evaluation, even when the therapist does not furnish a separately billable procedure in addition to the evaluation on this day,

would be considered treatment day one, effectively beginning the count of treatment days or calendar days for the first reporting period.

A treatment day is defined as a calendar day in which treatment occurs resulting in a billable service. Often a treatment day and a therapy ''session'' (or ''visit'') may be the same, but the two terms are not interchangeable. For example, a beneficiary might receive certain services twice a day, although this is a rare clinical scenario, these two different sessions (or visits) on the same day by the same discipline are counted as one treatment day.

We explained that the proposal would require that on the claim for service on or before the 10th treatment day or the 30th calendar day after treatment day one, the therapist would only report the G-code and the appropriate modifier to show the beneficiary's current functional status at the end of this reporting period under the proposal. We added that the next reporting period begins on the next treatment day and that the time period between the end of one reporting period and the next treatment day does not count towards the 30-calendar day period. On the claim for services furnished on this date, the therapist would report both the G-code and modifier showing the current functional status at this time along with the G-code and modifier reflecting the projected goal that was identified at the outset of the therapy episode. This process would continue until the beneficiary concludes the course of therapy treatment.

Further, we proposed that on a claim for a service that does not require specific reporting of a G-code with modifier (that is, on a claim for therapy services within the time period for which reporting is not required), GXXX7 would be used. By using this code, the therapist would be confirming that the claim does not require specific functional reporting. This is the only G-code that we proposed to be reported without a severity modifier.

As we noted in the proposed rule, we proposed the 10/30 frequency of reporting to be consistent with our existing timing requirements for progress reports. These timing requirements are included in the *Documentation Requirements for Therapy Services* (see Pub. 100–02, Chapter 15, Section 220.3, Subsection D). By making these reporting timeframes consistent with Medicare's other requirements, therapists who are already furnishing therapy services to Medicare outpatients would have a familiar framework for successfully adopting our new reporting requirement. In addition to reflecting the Medicare required documentation for progress reports, we believe that this simplifies the process and minimizes the new burden on therapists since many therapy episodes would be completed by the 10th treatment day. In 2008, the average number of days in a therapy episode was 9 treatment days for SLP, 11 treatment days for PT, and 12 treatment days for OT. Under the proposal, when reporting on two functional limitations, the therapist would report the G-codes and modifiers for the second condition in the manner described above. In other words, at the end of the reporting period as proposed, two G-codes would be reported to show current functional status—one for the primary (GXXX1) and one for the secondary (GXXX4) limitation. Similarly as proposed, at the beginning of the reporting period four G-codes would be reported. GXXX1 and GXXX4 would be used to report current status for the primary and secondary functional limitations, respectively; and, GXXX2 and GXXX5 would be used to report the goal status for the primary and secondary functional limitations, respectively.

We noted that the proposal required that the same reporting periods be used for both the primary and secondary functional limitation. We added that the therapist can accomplish this by starting them at the same time or if the secondary functional limitation is added at some point in treatment, the primary functional limitation's reporting period must be re-started by reporting GXXX1 and GXXX2 at the same time the new secondary functional limitation is added using GXXX4 and GXXX5.

Further, for those therapy treatment episodes lasting longer periods of time, the periodic reporting of the G-codes and associated modifiers would reflect any progress that the beneficiary made toward the identified goal. In summary, we proposed to require the reporting of G-codes and modifiers at episode outset (evaluation or initial visit), and once every 10th treatment day or at least every 30 calendar days, whichever time period is less, and at discharge.

We noted that we believed it was important that the requirements for this reporting system be consistent with the requirements for documenting any progress in the medical record as specified in our manual. Given the current proposal for claims-based data collection, we believe it is an appropriate time to reassess the manual requirements. We sought comment on whether it would be appropriate to modify the periodicity of the progress report requirement in the IOM to one based solely on the number of treatment days, such as six or ten. We noted that if a timing modification was made for progress reporting, a corresponding change would be made in the functional reporting interval.

The following is a summary of the comments we received on our proposal to require reporting every 10 treatment days or 30 calendar days, whichever is less, and whether it would be appropriate to modify the progress report requirement in the IOM to one based solely on the number of treatment days, such as six or ten, and the clinical impact of such a change.

Comment: Although many commenters appreciated our effort to align the claims-based reporting with existing requirements for a progress report, several commenters requested that we recognize the significant time burden of the new reporting frequency and that we ameliorate some of the burden with a simplification of the existing manual requirement. Commenters in favor of reporting every 10 treatment days explained that using treatment days as compared to calendar days is more easily programmed into software systems and in accord with certain therapist's billing practices. A couple of other commenters supported reporting every 30 calendar days as this accommodates therapists working in settings where claims are required to be submitted on a monthly basis, such as hospitals, rehabilitation agencies and SNFs. Several commenters objected to the periodic reporting and suggested that reporting only at the outset and at discharge of therapy would be sufficient to capture a beneficiary's functional progression. A few of those commenters were okay with the proposed 10 treatment day or 30 calendar day reporting timeframe, if periodic claims reporting is necessary.

A few commenters urged us to eliminate the requirement for functional status reporting at the visit subsequent to the progress report because a beneficiary's status probably would remain the same unless there is a significant gap between visits.

We received many comments concerning the reporting of GXXX7; which we proposed to be used to indicate that the therapist confirms functional reporting not required. These commenters stated that the reporting of GXXX7, which is required for claims with dates of services when a functional status measure is not collected, would be unnecessary and burdensome, especially for daily billers. They urged us to require reporting only when a functional status is required to be reported. Further commenters stated

that there was no purpose for this G-code.

Response: Based on the public comments, we are making several changes. We believe that reporting every 10 treatment days would be less burdensome for therapists than the proposed 10 treatment days/30 calendar days. We believe a 10 treatment day reporting period is straightforward for therapists to track, allows for better monitoring of changes in functional status, and is more easily adopted within our current claims processing systems. Therefore, we are finalizing the requirement that G-codes and associated modifiers are reported at least once every 10 treatment days and we will modify the IOM to establish the same timing requirement for progress reports. By making this change, we no longer need the therapist to report functional status at the visit subsequent to the end of a reporting period to signal the beginning of a new reporting period. So in response to comments, we have eliminated the requirement to report data at the start of a new reporting period.

After assessing the comments, we agree that reporting a G-code (GXXX7) to tell us that no reporting is required would not provide meaningful data and would pose an additional burden for therapists and therapy providers. When proposed, we believed it would be convenient for therapists to use the code to indicate that this was a claim for therapy services that did not require the functional reporting because it would assist them in complying with the reporting requirements and would assist us in enforcing them. When we reassessed the issue based on feedback from commenters, it was clear that the ''no report due'' code would not aid us in enforcing the requirements as we would still have to verify that claims with the proposed GXXX7 were in fact claims that did not require reporting. Since commenters pointed out that not only would it not assist them, but would in fact burden them, we have decided not to include this code. Accordingly, we are also modifying our proposal to remove the requirement to report a ''no report due'' code on claims when functional reporting is not due, such as between the first and the tenth day of service. We expect these changes will significantly reduce the frequency of required reporting during a therapy episode and believe they will appropriately simplify the claims-based reporting system.

- *Discharge.* In addition, we proposed to require reporting of the G-code/modifier functional data for the current status and for the goal at the conclusion of treatment so that we have a complete set of data for the therapy episode of care. Requiring the reporting at discharge mirrors the IOM requirement of a discharge note or summary. This set of data would reveal any functional progress or improvement the beneficiary made toward the projected therapy goal during the entire therapy episode. Specifically, information on the beneficiary's functional status at the time of discharge shows whether the beneficiary made progress towards or met the projected therapy goal. As we noted in the proposed rule, the imposition of this reporting requirement does not justify scheduling an additional and perhaps medically unnecessary final session in order to measure the beneficiary's function for the sole purpose of reporting.

Although collection of discharge data is important in achieving our goals, we recognize that data on functional status at the time therapy concludes is sometimes likely to be incomplete for some beneficiaries receiving outpatient therapy services. The DOTPA project has found this to be true. There are various reasons as to why the therapist would not be able to report functional status using G-codes and modifiers at the time therapy ends. Sometimes, beneficiaries may discontinue therapy without alerting their therapist of their intention to do so; simply because they feel better; they can no longer fit therapy into their life, work, or social schedules; a physician told them further therapy was not necessary; or their transportation is unavailable. Whatever the reason, there would be situations where the therapy ends without the planned discharge visit taking place. In these situations, we said that we would not require the reporting at discharge. However, we encourage therapists to include discharge reporting whenever possible on the final therapy claim for services.

Since the therapist is typically reassessing the beneficiary during the therapy episode, the data critical to the severity/complexity of the functional measure may be available even when the final therapy session does not occur. In these instances, the G-codes and modifiers appropriate to discharge should be reported when the final claim for therapy services has not already been submitted.

We sought feedback on how often the therapy community finds that beneficiaries discontinue therapy without the therapist knowing in advance that it is the last treatment session and other situations in which the discharge data would not be available for reporting.

The following is a summary of the comments we received regarding the proposal to require reporting of the G-code/modifier functional data at the conclusion of treatment so that we have a complete set of data for the therapy episode of care.

Comment: In addition to outset reporting, a majority of commenters supported claims-based reporting at discharge of the therapy episode of care. With regard to the number of beneficiaries who stop therapy services without notice, the responses varied from about 12 percent for beneficiaries being treated for a spinal cord injury to 26 percent of patients with orthopedic conditions in a large system of outpatient therapy clinics. Many commenters who supported discharge reporting recommended that if the beneficiary misses his or her last visit, the therapist should be exempt from reporting the functional status at discharge. Another commenter believed, however, that having a separate G-code in each set to report discharge status is unnecessary; the commenter further stated that the last reported current status and goal status G-codes could be used to represent the end of treatment.

Response: Although we recognize that there may be some challenges with discharge reporting, this information is important for our purposes to complete the data set for each therapy episode; and, thus, we are maintaining the requirement. We do not agree with the commenter who suggested that we could simply use the last reported current status to represent the status at discharge since this may not be an accurate representation of the beneficiary's status at the time of discharge. However, in those cases where this functional status is derived from a patient survey, for example, FOTO, Am-PAC or OPTIMAL, and the survey is routinely sent to the patient who misses his/her final treatment, the therapist should report this data once subsequently gained, on the final bill for services unless the bill for the last treatment day has already been submitted. There are instances where not reporting the discharge status would make it impossible for us to distinguish the start of the reporting for a new or subsequently-reported functional limitation or the treatment for a new therapy episode in the data. We are finalizing our proposal to require discharge reporting (except in cases where therapy services are discontinued by the beneficiary prior to the planned discharge visit) using the discharge G-code, along with the goal status G-code, to indicate the end of a therapy episode or to signal the end of reporting on one

functional limitation, while further therapy is necessary for another one.

• *Significant Change in Beneficiary Condition.* We proposed that, in addition to reporting at the intervals discussed above, the G-code/modifier measures would be required to be reported when a formal and medically necessary re-evaluation of the beneficiary results in an alteration of the goals in the beneficiary's POC. This could result from new clinical findings, an added comorbidity, or a failure to respond to treatment. We noted that this reporting affords the therapist the opportunity to explain a beneficiary's failure to progress toward the initially established goal(s) and permits either the revision of the severity status of the existing goal or the establishment of a new goal or goals. Under the proposal, the therapist would be required to begin a new reporting period when submitting a claim containing a CPT code for an evaluation or a re-evaluation. This functional reporting of G-codes, along with the associated modifiers, could be used to show an increase in the severity of functional limitations; or, they could be used to reflect the severity of newly identified functional limitations as delineated in the revised plan of care.

The following is a summary of the comments we received regarding the proposal that in addition to reporting at the intervals discussed above, the G-code and related modifier would be required to be reported when a formal and medically necessary re-evaluation of the beneficiary results in an alteration of the goals in the beneficiary's POC.

Comment: One commenter recommended that instead of requiring periodic reporting throughout a therapy episode that we require it only at the time of a re-evaluation. This commenter believed that capturing the functional information using G-codes within the treatment episode is burdensome and reporting at the time of the progress report would put unnecessary emphasis on a therapist capturing a change in a beneficiary's assessment.

Response: We did not receive comments objecting to claims-based reporting at the time that a re-evaluation code is billed for PT or OT or a subsequent or second evaluation code is billed for SLP. Therefore, we are finalizing the requirement for functional reporting when a formal and medically necessary re-evaluation, for PT or OT, or a second or repeat SLP evaluation of the beneficiary is furnished. We are requiring claims-based reporting in conjunction with the evaluation at the outset of therapy, on or before each 10th treatment day throughout therapy, and at therapy discharge (except in cases where therapy services are unexpectedly discontinued by the beneficiary prior to the planned discharge visit and the necessary information is not available) or to signal the end of reporting on one functional limitation. On a claim, two G-codes would be required depending on the reporting interval. Table 25 shows a revised example of which codes are used for specified reporting under our final policy. We should note that this example utilizes the mobility functional limitation G-codes, G8978–G8980 for ''walking and moving around'' and the ''Other or Primary'' G-codes, G8990–G8992 and is for illustrative purposes only. This table not only shows how the final reporting works but by comparing it to the table showing the same details for reporting under the proposed policy one can see how much less reporting is required. Any of the other functional limitation G-code sets listed in Table 21 would also be applicable here.

TABLE 25: Example of Required Reporting

	Evaluation/Treatment Day One, Begin Reporting Period #1	End Reporting Period #1	Reporting Period #2 Begins Next Treatment Day	Claim for treatment days 5 and 6 in Period #2	End Reporting Period #2	Reporting Period #3 Begins Next Treatment Day	Discharge /End of reporting on Walking & Moving Around Functional Limitation	Begin Reporting Period #1 for Other Primary
Mobility: Walking & Moving Around								
G8978 – Current	X	X			X			
G 8979– Goal	X	X			X		X	
G8980 – Discharge							X	
Other Primary								
G8990 – Current								X
G8991 – Goal								X
G8992 – Discharge								
No Functional Reporting Required								
No coding exists.								

In summary, we maintain that claims-based reporting should occur at the outset of therapy episode, on or before every 10 treatment days throughout the course of therapy, and at the time of discharge from therapy. Additionally, functional reporting is also required at the time the beneficiary's condition changes significantly enough to clinically warrant a re-evaluation such that a HCPCS/CPT code for a re-evaluation or a repeat evaluation is billed.

(7) Documentation

We proposed to require that documentation of the information used for reporting under this system must be included in the beneficiary's medical record. As proposed, the therapist would need to track in the medical record the G-codes and the corresponding severity modifiers that were used to report the status of the functional limitations at the time reporting was required. Including G-codes and related modifiers in the medical record creates an auditable record, assists in improving the quality of data CMS collects, and allows therapists to track assessment and functional information. In the proposed rule, we provided the example of a situation where the therapist selects the mobility functional limitation of ''walking and moving'' as the primary functional limitation and determines that at therapy outset the beneficiary has a 60 percent limitation and sets the goal to reduce the limitation to 5 percent. We noted that the therapist uses GXXX1–XH to report the current status of the functional impairment and GXXX2–XB to report the goal. Additionally, we said that the therapist should note in the beneficiary's medical record that the functional limitation is ''walking and moving'' and document the G-codes and severity modifiers used to report this functional limitation on the claim for therapy services.

The following is a summary of comments we received concerning our documentation requirements.

Comment: Some commenters suggested that the proposal would impose significant additional documentation and claims reporting requirements. Further, one commenter objected to the requirement to include information in the medical record on the G-codes and modifiers used for billing as it would be highly unusual and time intensive to do so. Another commenter supported our proposal, agreeing that documentation of the information used for reporting under this system must be included in the beneficiary's medical record.

Response: We disagree with the commenters' statements that the required documentation is overly burdensome. In fact, by maintaining the G-code descriptor and related modifier in the medical record, therapists may find it easier to link treatment and reporting. Additionally, to enforce the reporting requirements on the claims, documentation in the medical record is required. In cases where the therapist uses other information in addition to certain measurement tools in order to assess functional impairment, he or she would also want to document the relevant information used to determine the overall percentage of functional limitation to select the severity modifier. In instances where it becomes necessary for a different therapist to furnish the therapy services, the substitute therapist can look in the beneficiary's medical record to note previous G-codes and related modifiers

reported. We are finalizing the proposed requirement that the G-codes and related modifiers must be documented in the beneficiary's medical record.

(8) Claims Requirements

In the proposed rule, we noted that except for the addition of the proposed G-codes and the associated modifiers, nothing in this proposal would modify other existing requirements for submission of therapy claims. We noted in the proposed rule that, in addition to the new G-codes and modifiers used for the claims-based data collection system, the therapy modifiers—GO, GP, and GN, would still be required on claims to indicate that the therapy services are furnished under an OT, PT, or SLP plan of care, respectively; and, therefore, we are designating these nonpayable G-codes as ''always therapy.'' We noted in the proposed rule that institutional claims for therapy services would require that a charge be included on the service line for each one of these G-codes used in the required functional reporting. We also noted that this charge would not be used for payment purposes and would not affect processing. Further, we noted claims for professional services do not require that a charge be included for these nonpayable G-codes, but that reporting a charge for the nonpayable G-codes would not affect claims processing. To illustrate this policy, for each nonpayable G-code on the claim, that line of service would also need to contain one of the severity modifiers, the corresponding GO, GP, or GN therapy modifier to indicate the respective OT, PT, or SLP therapy discipline and related POC; and the date of service it references. For each line on the institutional claim submitted by hospitals, SNFs, rehabilitation agencies, CORFs and HHAs, a charge of one penny, $0.01, can be added. For each line on the professional claim submitted by private practice therapists and physician/NPPs, a charge of $0.00 can be added. We believe that many therapists submitting professional claims are already submitting nonpayable G-code quality measures under the PQRS and will be familiar with the parameters of nonpayable G-codes on claims for Medicare services.

Finally, we noted that Medicare does not process claims that do not include a billable service. As a result, reporting under this claims-based data collection system would need to be included on the same claim as a furnished service that Medicare covers.

We did not receive any comments specifically on the claims requirements so we are finalizing these as proposed.

(9) Implementation Date

In accordance with section 3005(g) of the MCTRJCA, we proposed to implement these data reporting requirements on January 1, 2013. We recognized that with electronic health records and electronic claims submission, therapists might encounter difficulty in including this new data on claims. To accommodate those that may experience operational or other difficulties with moving to this new reporting system and to assure smooth transition, we proposed a testing period from January 1, 2013 until July 1, 2013. We noted that we would expect that all those billing for outpatient therapy services would take advantage of this testing period and would begin attempting to report the new G-codes and modifiers as close to January 1, 2013, as possible, in preparation for required reporting beginning on July 1, 2013. Taking advantage of this testing period would help to minimize potential problems after July 1, 2013, when claims without the appropriate G-codes and modifiers would be returned unpaid.

The following is a summary of comments we received concerning our implementation of the new system on January 1, 2013 with enforcement beginning after July 1, 2013.

Comment: Given the statutory deadline, most commenters acknowledged that the new program needed to be implemented on January 1, 2013. Many commenters supported the proposed testing period. They indicated that a testing period was needed to train therapists, change documentation practices, modify electronic health records systems, educate billing contractors, and adjust billing systems. However, numerous commenters expressed concern that 6 months is an insufficient and unrealistic amount of time to transition to the new data reporting requirements. Commenters requested that we recognize the significant time and financial burden of the new reporting requirement and that we alleviate these concerns with delayed enforcement. Commenters requested a longer period to make software adjustments and educate therapists on the new reporting and frequency of documentation requirements. Further, commenters believed that we, in the limited time period, did not recognize the potential capital changes that would be necessary or allow for the typical process for acquiring funds. Commenters proposed various alternatives, which included extending the testing period to 9 or 12 months. A few suggested that we delay implementation of the mandate until the completion of the DOTPA study. As an alternative to nationwide data reporting, a few commenters suggested we consider testing the requirement under a pilot program in a small sample of the country, allowing us to analyze preliminary data and draw conclusions regarding the effectiveness of reporting through non-payable G-codes and modifiers before it is implemented nationwide.

Response: We are required by law to implement the claims-based data collection strategy on January 1, 2013. Our contractors and systems will be able to accept and process claims for therapy services with functional information at this time. We recognize that therapists may need time to adjust their claims processing to accommodate these additional codes but, we believe the necessary changes can be accomplished well within the 8 months between the time this final rule with comment period is issued and the end of the testing period. We do not believe a small pilot as suggested by some commenters would meet the statutory requirement to implement as of January 1, 2013 a claims-based data collection strategy to assist in reforming outpatient therapy services. Nor would it meet our needs to gather data to assist in developing potential alternative payment systems for therapy services. We are finalizing an implementation date of January 1, 2013 with a 6-month testing period such that claims that do not comply with the data reporting requirements will be returned beginning July 1, 2013.

(10) Compliance Required as a Condition for Payment and Regulatory Changes

To implement the claims-based data collection system required by MCTRJCA and described above, we proposed to amend the regulations establishing the conditions for payment governing outpatient and CORF PT, OT, and SLP services to add a requirement that the claims include information on beneficiary functional limitations. In addition, we proposed to amend the POC requirements set forth in the regulations for outpatient therapy services and CORFs to require that the therapy goals, which must be included in the POC, are consistent with the beneficiary's functional limitations and goals reported on claims for services.

Specifically, we proposed to amend the regulations for outpatient OT, PT, and SLP (§ 410.59, § 410.60, and § 410.62, respectively) by adding a new paragraph (a)(4) to require that claims submitted for services furnished contain

the required information on beneficiary functional limitations.

We also proposed to amend the POC requirements set forth at § 410.61(c) to require that the therapy goals, which must be included in the treatment plan, must be consistent with those reported on claims for services. This requirement is in addition to those already existing conditions for the POC.

To achieve consistency in the provision of PT, OT, and SLP services across therapy benefits, we proposed to amend § 410.105 to include the same requirements for these services furnished in CORFs. These proposed revisions would require that the goals specified in the treatment plan be consistent with the beneficiary functional limitations and goals reported on claims for services and that claims submitted for services furnished contain specified information on beneficiary functional limitations, respectively. The requirements do not apply to respiratory therapy services.

We did not receive any comments on the proposed regulatory changes and are finalizing the changes as proposed.

(11) Consulting With Relevant Stakeholders

Section 3005(g) of the MCTRJCA requires us to consult with relevant stakeholders as we propose and implement this reporting system. In the CY 2013 PFS proposed rule, we indicated that we are meeting this requirement through the publication of this proposal and specifically by soliciting public comment on the various aspects of our proposal. In addition, we noted that we would meet with key stakeholders and discuss this issue in Open Door Forums over the course of the summer.

During the CY 2013 proposed rule comment period, we met with the various therapy professional associations and provider groups in order to solicit their comments on the various aspects of this proposal. At the CMS Physicians, Nurses & Allied Health Professionals Open Door Forum on July 17, 2012, we discussed the provisions of the proposed rule, including these requirements. We also discussed this proposed rule at the CMS Hospital & Hospital Quality Open Door Forum on July 18, 2012. In developing the final rule, we took into consideration many of the critical issues that were raised by the various stakeholders in these meetings and Forums. Accordingly, we believe we have met our obligation to consult with relevant stakeholders in proposing and implementing the required claims-based data collection strategy, and in developing our final policies, we have taken into consideration the various needs of stakeholders affected by this effort.

H. Primary Care and Care Coordination

In recent years, we have recognized primary care and care coordination as critical components in achieving better care for individuals, better health for individuals, and reduced expenditure growth. Accordingly, we have prioritized the development and implementation of a series of initiatives designed to improve payment for, and encourage long-term investment in, primary care and care management services. These initiatives include the following programs and demonstrations:

- The Medicare Shared Savings Program (described in ''Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule'' which appeared in the **Federal Register** on November 2, 2011 (76 FR 67802)).

++ The testing of the Pioneer ACO model, designed for experienced health care organizations (described on the Center for Medicare and Medicaid Innovation's (Innovation Center's) Web site at *innovations.cms.gov/initiatives/ACO/Pioneer/index.html*).

++ The testing of the Advance Payment ACO model, designed to support organizations participating in the Medicare Shared Savings Program (described on the Innovation Center's Web site at *innovations.cms.gov/initiatives/ACO/Advance-Payment/index.html*).

- The Primary Care Incentive Payment (PCIP) Program (described on the CMS Web site at *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/PCIP-2011-Payments.pdf*).

- The patient-centered medical home model in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration designed to test whether the quality and coordination of health care services are improved by making advanced primary care practices more broadly available (described on the CMS Web site at *www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf*).

- The Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration (described on the CMS Web site at *www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf* and the Innovation Center's Web site at *innovations.cms.gov/initiatives/FQHCs/index.html*).

- The Comprehensive Primary Care (CPC) initiative (described on the Innovation Center's Web site at *innovations.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/index.html*). The CPC initiative is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care in certain markets across the country.

In coordination with these initiatives, we also continue to explore other potential refinements to the PFS that would appropriately value primary care and care coordination within Medicare's statutory structure for fee-for-service physician payment and quality reporting. We believe that improvements in payment for primary care and recognizing care coordination initiatives are particularly important as EHR technology diffuses and improves the ability of physicians and other providers of health care to work together to improve patient care. We view these potential refinements to the PFS as part of a broader strategy that relies on input and information gathered from the initiatives described above, research and demonstrations from other public and private stakeholders, the work of all parties involved in the potentially misvalued code initiative, and from the public at large.

In the CY 2012 PFS proposed rule (76 FR 42793 through 42794), we initiated a discussion to gather information about how primary care services have evolved to focus on preventing and managing chronic conditions. We also proposed to review evaluation and management (E/M) services as potentially misvalued and suggested that the American Medical Association Relative (Value) Update Committee (AMA RUC) might consider changes in the practice of chronic conditions management and care coordination as key reason for undertaking this review. In the CY 2012 PFS final rule with comment period (76 FR 73062 through 73065), we did not finalize our proposal to review E/M codes due to consensus from an overwhelming majority of commenters that a review of E/M services using our current processes could not appropriately value the evolving practice of chronic care coordination at the time, and therefore, would not accomplish the agency's goal of paying appropriately for primary care services. We stated that we would continue to consider ongoing research projects, demonstrations, and the numerous policy alternatives suggested by commenters. In addition, in the CY 2012 PFS proposed rule (76 FR 42917 through 42920), we initiated a public