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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Comments Due: 8/24/10

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 409, 410, 411, 413, 414, 415, and 424

[CMS-1503-P]

RINs 0938-AP79

Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011

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

ACTION: Proposed rule.

SUMMARY: This proposed rule addresses proposed changes to the physician fee schedule and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. It also addresses, implements or discusses certain provisions of both the Affordable Care Act and the Medicare Improvements for Patients and Providers Act of 2008. In addition, this proposed rule discusses payments under the Ambulance Fee Schedule, Clinical Laboratory Fee Schedule, payments to ESRD facilities, and payments for Part B drugs. Finally, the proposed rule includes a discussion regarding the Chiropractic Services Demonstration program, the Competitive Bidding Program for Durable Medical Equipment and Provider and Supplier Enrollment Issues associated with Air Ambulances. (See the Table of Contents for a listing of the specific issues addressed in this proposed rule.)

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR—insert date 60 days after the date of filing for public inspection at OFR.]

number miles on both paper and electronic claims. We propose that providers and suppliers would round up fractional mileage to the next whole number for mileage that exceeds 100 covered miles and report the resulting whole number in the units' field. We would revise the instructions set forth in our Claims Processing Manual to reflect the revised procedures for submitting and paying claims for fractional ambulance.

C. Clinical Laboratory Fee Schedule: Signature on Requisition

In the March 10, 2000 **Federal Register**, we published the "Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services" proposed rule (65 FR 13082) announcing and soliciting comments on the results of our negotiated rulemaking committee tasked to establish national coverage and administrative policies for clinical diagnostic laboratory tests under Part B of Medicare. In our final rule published in the November 23, 2001 **Federal Register** (66 FR 58788), we explained our policy on ordering clinical diagnostic laboratory services and amended §410.32 to make our policy more explicit. Our regulation at §410.32(a) states the requirement that "[a]ll diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary." In the November 23, 2001 final rule, we added paragraph (d)(2) to §410.32 to require that the physician or qualified nonphysician practitioner (NPP) (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners (NPs), and physician assistants (PAs)) who orders the service must maintain documentation of medical necessity in the beneficiary's medical record (66 FR 58809). In the preamble discussions to the March 10, 2000 proposed rule and November 23, 2001 final rule (65 FR 13089 and 66 FR 58802, respectively), we noted that "[w]hile the signature of a physician on a requisition is one way of documenting that the treating

physician ordered the test, it is not the only permissible way of documenting that the test has been ordered." In those preambles, we described the policy of not requiring physician signatures on requisitions for clinical diagnostic laboratory tests, but implicitly left in place the existing requirements for a written order to be signed by the ordering physician or NPP for clinical diagnostic laboratory tests, as well as other types of diagnostic tests. We further stated in the preambles of the proposed and final rules that we would publish an instruction to Medicare contractors clarifying that the signature of the ordering physician is not required for Medicare purposes on a requisition for a clinical diagnostic laboratory test (65 FR 13089 and 66 FR 58802).

On March 5, 2002, we published a program transmittal implementing the administrative policies set forth in the final rule, including the following instruction: "Medicare does not require the signature of the ordering physician on a laboratory service requisition. While the signature of a physician on a requisition is one way of documenting that the treating physician ordered the service, it is not the only permissible way of documenting that the service has been ordered. For example, the physician may document the ordering of specific services in the patient's medical record." (Transmittal AB-02-030, Change Request 1998, dated March 5, 2002).

On January 24, 2003, we published a program transmittal in order to manualize the March 5, 2002 Transmittal. (Transmittal 1787, Change Request 2410, dated January 24, 2003). The cover note to the transmittal states, "Section 15021, Ordering Diagnostic Tests, manualizes Transmittal AB-02-030, dated March 5, 2002. In accordance with negotiated rulemaking for outpatient clinical diagnostic laboratory services, no signature is required for the ordering of such services or for physician pathology services." In the manual instructions in that transmittal in a note, we stated:

"No signature is required on orders for clinical diagnostic services paid on the basis of the physician fee schedule or for physician pathology services." The manual instructions did not explicitly reference clinical diagnostic laboratory tests as the cover note did. Rather, the transmittal seemed to extend the policy set forth in the **Federal Register** (that no signature is required on requisitions for clinical diagnostic laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS)) to also apply to clinical diagnostic tests paid on the basis of the Physician Fee Schedule (PFS) and physician pathology services. In addition, the manual instructions used the term "order" instead of "requisition," which some members of the industry have asserted caused confusion.

When we transitioned from paper manuals to the current electronic Internet Only Manual system, these manual instructions were inadvertently omitted from the new Benefit Policy Manual (BPM).

In August 2008, we issued a program transmittal (Transmittal 94, Change Request 6100, dated August 29, 2008) to update the BPM to incorporate language that was previously contained in section 15021 of the Medicare Carriers Manual. The reissued language states, "No signature is required on orders for clinical diagnostic tests paid on the basis of the clinical laboratory fee schedule, the physician fee schedule, or for physician pathology services." Based on further review, we have determined that there are no clinical diagnostic laboratory tests paid under the PFS. After Transmittal 94 was published, we received numerous inquiries from laboratory, diagnostic testing, and hospital representatives who had questions about whether the provision applied to all diagnostic services, including x-rays, MRIs, and other nonclinical laboratory fee schedule diagnostic services.

To resolve any existing confusion surrounding the implementation of the policy in 2001 and subsequent transmittals, we restated and solicited public comments on our policy in the CY 2010 PFS proposed rule (74 FR 33641). Our current policy is that a physician's signature is not required on a requisition for clinical diagnostic laboratory tests paid on the basis of the CLFS; however, it must be evident, in accordance with our regulations at §410.32(d)(2) and (3), that the physician ordered the services.

We note that we solicited and received comments on this signature requirement during the notice and comment period for the March 10, 2000 proposed rule in the context of our proposal to add paragraph (d)(2)(i) to §410.32 to require that the practitioner who orders a diagnostic laboratory test must maintain documentation of medical necessity in the beneficiary's medical record. The majority of comments supported the adoption of a policy that the signature of the practitioner on a requisition for a clinical diagnostic laboratory test paid under the CLFS is not the only way of documenting that the test has been ordered and, thus, should not be required provided such documentation exists in an alternate form.

This policy regarding requisitions for clinical diagnostic laboratory tests does not supersede other applicable Medicare requirements (such as those related to hospital Conditions of Participation (CoPs)) which require the medical record to include an order signed by the physician who is treating the beneficiary. Nor do we believe that anything in our policy regarding signatures on requisitions for clinical diagnostic laboratory tests supersedes other requirements mandated by professional standards of practice or obligations regarding orders and medical records promulgated by Medicare, the Joint Commission, or State law; nor do we believe the policy would require providers to change their business practices.

We also restated and solicited public comment on our long-standing policy consistent with the principle in §410.32(a) that a written order for diagnostic tests including those paid under the CLFS and those that are not paid under the CLFS (for example, that are paid under the PFS or under the OPPS), such as X-rays, MRIs, and the TC of physician pathology services, must be signed by the ordering physician or NPP. That is, the policy that signatures are not required on requisitions for clinical diagnostic laboratory tests paid based on the CLFS applies only to requisitions (as opposed to written orders) (74 FR 33642).

Additionally, we solicited public comments about the distinction between an order and a requisition (74 FR 33642). We note that an "order" as defined in our IOM, 100-02, Chapter 15, Section 80.6.1, is a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary. The order may conditionally request an additional diagnostic test for a particular beneficiary if the result of the initial diagnostic test ordered yields to a certain value determined by the treating physician/practitioner (for example, if test X is negative, then perform test Y). As set forth in the CY 2010 MPFS final rule (FR 74 61930), an order may be delivered via any of the following forms of communication:

- A written document signed by the treating physician/practitioner, which is hand-delivered, mailed, or faxed to the testing facility.
- A telephone call by the treating physician/practitioner or his or her office to the testing facility.
- An electronic mail, or other electronic means, by the treating physician/practitioner or his or her office to the testing facility.

If the order is communicated via telephone, both the treating physician/practitioner, or his or her office, and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records.

In the proposed rule (74 FR 33642), we defined a "requisition" as the actual paperwork, such as a form, which is provided to a clinical diagnostic laboratory that identifies the test or tests to be performed for a patient. It may contain patient information, ordering physician information, referring institution information, information about where to send reports, billing information, specimen information, shipping addresses for specimens or tissue samples, and checkboxes for test selection. We believe it is ministerial in nature, assisting laboratories with billing and handling of results, and serves as an administrative convenience to providers and patients. We believe that a written order, which may be part of the medical record, and the requisition are two different documents, although a requisition that is signed may serve as an order. We welcomed comments from the public about the distinction between requisitions and orders.

During the proposed and final rulemaking process for CY 2010, we received numerous comments on these issues, including, among others: expressions of continued confusion over the difference between an "order" and a "requisition"; requests that CMS develop a single policy for all outpatient laboratory services, without the distinction for those paid under the CLFS or the PFS; and concerns about reference laboratory technicians who felt compelled to perform a test in order to protect the viability of the specimen although they did not have the proper documentation. See 74 FR 61930-32 for a complete discussion of the comments received and responses to these issues. In the CY 2010 PFS final rule with comment period (74 FR 61931), we stated that, in light of the

issues and concerns raised during the comment period, and our desire to create policy that will address the concerns in a meaningful, clear and thoughtful way, we would continue to carefully consider the issues of physician signatures on requisitions and orders and that we plan to revisit these issues in the future paying particular attention to the definitions of order and requisition.

Since the publication of the CY 2010 PFS final rule with comment period, we have considered an approach that would address the concerns raised. We are proposing to require a physician's or NPP's signature on requisitions for clinical diagnostic laboratory tests paid on the basis of the CLFS.

We believe that this policy would result in a less confusing process. We believe that it would be less confusing because a physician's signature would then be required for all requisitions and orders, eliminating uncertainty over whether the documentation is a requisition or an order, whether the type of test being ordered requires a signature, or which payment system does or does not require a physician or NPP signature. We also believe that it would not increase the burden on physicians because it is our understanding that, in most instances, physicians are annotating the patient's medical record with either a signature or an initial (the "order"), as well as providing a signature on the paperwork that is provided to the clinical diagnostic laboratory that identifies the test or tests to be performed for a patient (the "requisition") as a matter of course. Further, this policy would make it easier for the reference laboratory technicians to know whether a test is appropriately requested, and potential compliance problems would be minimized for laboratories during the course of a subsequent Medicare audit because a signature would be consistently required. As already discussed, this minimizes confusion and provides a straightforward directive for laboratories to meet.

We welcome comments on this proposal.

D. Discussion of Chiropractic Services Demonstration

Section 651 of MMA requires the Secretary to conduct a 2-year demonstration to evaluate the feasibility and advisability of expanding coverage for chiropractic services under Medicare. Medicare coverage for chiropractic services is limited to manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Act. The demonstration expanded current Medicare coverage to include "care for neuromusculoskeletal conditions typical among eligible beneficiaries and diagnostic and other services that a chiropractor is legally authorized to perform by the State or jurisdiction in which such treatment is provided" and was conducted in four geographically diverse sites, two rural and two urban regions, with each type including a Health Professional Shortage Area (HPSA). The two urban sites were 26 counties in Illinois and Scott County, Iowa, and 17 counties in Virginia. The two rural sites were the States of Maine and New Mexico. The demonstration, which ended on March 31, 2007, was required to be budget neutral as section 651(f)(1)(B) of MMA mandates the Secretary to ensure that "the aggregate payments made by the Secretary under the Medicare program do not exceed the amount which the Secretary would have paid under the Medicare program if the demonstration projects under this section were not implemented."

In the CY 2006, 2007, and 2008 PFS final rules with comment period (70 FR 70266, 71 FR 69707, 72 FR 66325, respectively), we included a discussion of the strategy that would be used to assess budget neutrality (BN) and the method for adjusting chiropractor fees in the event the demonstration resulted in costs higher than those that would occur in the absence of the demonstration. We stated BN would be assessed by