40160), we are applying the fractional unit billing policy only to ambulance mileage.

5. Final Fractional Mileage Billing Policy

For the reasons discussed above and in the CY 2011 PFS proposed rule (75 FR 40159), we believe that it is reasonable and appropriate to implement the fractional mileage billing policy as proposed in the CY 2011 PFS proposed rule effective for claims with dates of service on and after January 1, 2011 (with the exception discussed below relating to providers billing on paper Form UB–04).

Therefore, effective for claims with dates of service on and after January 1, 2011, ambulance providers and suppliers (except for providers billing on paper Form UB–04) are required to report mileage rounded up to the nearest tenth of a mile on all claims for mileage totaling up to 100 covered miles. Providers and suppliers must submit fractional mileage using a decimal in the appropriate place (for example, 99.9). For example, if the total miles traveled equals 1.59 miles, then the provider or supplier must report "1.6" on the claim for mileage. Likewise, if the total mileage equals 1.53 miles, the provider or supplier must report "1.6" on the claim.

Although the electronic claim formats can accommodate fractional mileage when mileage is equal to or greater than 100 covered miles (for example, 100.0), as discussed in the proposed rule, the paper claim cannot. The Form CMS–1500 paper claim currently only supports four characters (including the decimal point) in the units field (Item 24G). Therefore, we are finalizing our proposal that mileage equal to or greater than 100 covered miles must continue to be reported in whole number miles on both paper and electronic claims. Providers and suppliers must round up fractional mileage to the next whole number for mileage that exceeds 100 covered miles and report the resulting whole number in the unit field. The instructions set forth in our Claims Processing Manual will be updated to reflect the revised procedures for submitting and paying claims for fractional ambulance mileage.

Because the changes to the paper Form UB–04 necessary to accommodate fractional units are scheduled to be completed in July 2011, implementation of this policy for ambulance providers that are permitted to bill using the Form UB–04 is delayed until August 1, 2011 (that is, ambulance providers permitted to bill on paper form UB–04 will be required to report fractional mileage in accordance with this final rule with comment period for dates of service on and after August 1, 2011). If the paper Form UB–04 is not capable of accepting fractional mileage by July 31, 2011, then implementation of this policy for these ambulance providers will be further delayed until January 1, 2012. As with other claim types, upon implementation of the fractional mileage policy for providers billing on the paper Form UB–04, these providers will report fractional mileage on all claims for mileage totaling up to 100 miles.

As discussed previously, providers and suppliers are responsible for ensuring that they have the necessary equipment to measure fractional mileage to the tenth of a mile, and ensuring that onboard vehicle gauges measuring trip mileage are in working order. If they are not able to repair said gauges, they are responsible for ensuring that they have the necessary equipment to measure mileage accurate to the tenth of a mile. Tools that may be used to measure trip mileage include, but are not limited to: Digital or analog odometers, trip odometers, GPS navigation, onboard trip computers or navigation systems.

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 order 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 CLFS) to also apply to clinical diagnostic tests paid on the basis of the 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 CLFS, the physician fee schedule, or for physician pathology services." Based on further review, we 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 (TJC), 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 longstanding 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 PFS 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 CY 2010 PFS 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 we 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 believed 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 61929 through 61931 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. Therefore, in the CY 2011 PFS proposed rule (75 FR 40162), we proposed to require a physician's or NPP's signature on requisitions for clinical diagnostic laboratory tests paid on the basis of the CLFS. We stated that we believe that this policy would result in a less confusing process 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 stated that we 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, we stated that 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. We stated in the CY 2011 OPPS/ASC proposed rule that this minimizes confusion and provides a straightforward directive for laboratories to meet.

Comment: Some commenters stated that physicians continue to be unfamiliar with when a signature is required and when it is not required on requisitions for physician pathology services, x-ray services, and services other than clinical diagnostic laboratory tests paid under the CLFS. The commenters also asked for consistency in signature requirements between services required under the CLFS and the Physician Fee Schedule (PFS).

Response: We proposed to require a physician's or NPP's signature on requisitions for clinical diagnostic laboratory tests paid under the CLFS. We did not propose to change, and we are not changing, the signature requirements for other services. One of the reasons we made this proposal is because we believed that it would be less confusing for a physician's signature to 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.

Comment: Some commenters were supportive of our proposal.

Response: We appreciate the commenters' support of our proposed policy, which we are finalizing in this rule.

Comment: The commenters seemed to interpret the proposed policy to mean that clinical diagnostic laboratory tests requested by telephone or electronic means would not be acceptable because they would not contain a signature. The commenters stated that there must be a way to validate electronic requests for services by the physician or NPP and that, as the medical world moves toward electronic records, everything must be annotated (that is, "signed") in some way to authenticate that the service is ordered by the physician.

Response: Our proposed policy does not concern electronic or telephonic requests, because we do not consider these types of requests to be requisitions. As we discussed previously, a requisition is the actual paperwork, such as a form, that 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 the billing and handling of results, and serves as an administrative convenience to providers and patients. When a physician or NPP chooses to use a requisition to request a clinical diagnostic laboratory test paid under the CLFS, under the policy we are adopting in this rule, the physician or NPP must sign the requisition.

Comment: The commenters pointed out that it should be evident from the medical record that the physician actually ordered the service.

Response: We did not propose to change any requirements with respect to orders. As discussed above, a requisition is 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. Our proposal only applies to signatures on requisitions for clinical diagnostic laboratory tests paid under the CLFS. A signature on a requisition should be sufficient for a clinical diagnostic laboratory to verify that a physician or NPP is requesting a clinical diagnostic laboratory test.

Comment: The commenters stated that the patient rarely takes the requisition to the laboratory himself/herself because the patient does not go to the laboratory. These commenters seemed to believe that, in those cases, a paper request for clinical diagnostic laboratory services would have to be created where there may not have been a need for one to exist. The commenters suggested that only the medical record, and not any other paper materials, should be signed or initialed by the physician.

Response: As stated previously, a requisition is 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. Under our proposed policy, which we are finalizing in this rule, if a physician or NPP chooses to use a requisition to request a clinical diagnostic laboratory test paid under the CLFS, the physician or NPP must sign the form. However, this policy does not require a physician or NPP to use a requisition to request a clinical diagnostic laboratory test paid under the CLFS. Many physicians and NPPs currently request clinical diagnostic laboratory tests using an order, such as an annotated medical record or documented telephonic request, and they may continue to do so without being impacted by our new policy for requisitions.

Comment: The commenters suggested that physicians would need to be educated about the new signature requirement on requisitions for clinical diagnostic laboratory tests paid under the CLFS to alleviate problems such as physician non-compliance with this policy because they are unaware of it or do not understand it. Some commenters stated that they firmly believe that the physician will neglect to sign any document that directs the clinical diagnostic laboratory to perform a service. In order to incentivize physicians to provide a signature, some commenters suggested tying the physician's ability to bill for a service to the requirement to provide a signature.

Response: We understand the need to educate physicians and NPPs. As such, in addition to updating our manuals, we will direct the Medicare contractors to educate physicians and NPPs concerning this issue. We did not propose to adopt a policy linking the physician's ability to bill for a service to the requirement to provide a signature

and we are not adopting such policy in this final rule.

Comment: The commenters believe that medical personnel are already required to provide an extensive amount of identifying information on the requisition. The commenters stated that either the physician or NPP is completing the paperwork but then, in most cases, not signing it or initialing it to confirm that the required service was documented by a medical practitioner.

Response: If physicians and NPPs are completing extensive written documentation concerning each beneficiary on requisitions, the addition of a signature should not be an issue.

Comment: The commenters expressed continued confusion over the terms "requisition" and "order." The commenters stated that CMS should define "requisition" and "order" in the CMS Internet Only Manual (IOM) system.

Response: We recognize that there is confusion around the definition of these terms. However, as we stated above, we define an "order" (IOM, 100–02, Chapter 15, Section 80.6.1) as a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary. We further provided that an order may be delivered via any of the following forms of communication: (1) A written document signed by the treating physician/practitioner, which is hand-delivered, mailed, or faxed to the testing facility; (2) a telephone call by the treating physician/practitioner or his or her office to the testing facility; or (3) 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. We define 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 are revising our manuals to reflect our new requirement for physicians' and NPPs' signatures on requisitions for clinical diagnostic laboratory tests paid under the CLFS.

Comment: The commenters note that there is no corresponding suggested change in the language of the Code of Federal Regulations (CFR) concerning the physician signature issue.

Response: We have determined that a change to § 410.32(d)(2) is not necessary with respect to this issue because this provision involves orders not requisitions. We articulated our policy regarding requisitions for clinical diagnostic laboratory tests in our manuals and in preamble language. Therefore, we are changing our manuals to reflect our new policy.

Comment: The commenters suggested that the requirement to provide some type of signature represents an undue burden on the clinical diagnostic laboratory, especially in the long term care world where standing orders in the form of a "plan of care" are maintained in the beneficiary's records onsite and tests are ordered by the long term care staff as required based on directions provided by the physician. The commenters asserted that the physician rarely appears onsite at the facility to sign requests for medical services and, as a result, an exception for these types of facilities is warranted. However, commenters also pointed to a Drug Enforcement Administration (DEA) requirement for long term care facilities which states that, "The facility must provide or obtain laboratory services only when ordered by the attending physician."

Response: Again, the change in policy discussed in this final rule only affects requisitions and does not affect orders. The policy that we proposed and are adopting as final in this rule is that a physician's or NPP's signature is required on requisitions for clinical diagnostic laboratory tests paid under the CLFS.

Comment: The commenters suggested that the following language was clear and should stand as the entire policy here: "A physician's signature is not required on a requisition for clinical diagnostic laboratory tests paid on the basis of the Clinical Laboratory Fee Schedule (CLFS); however, it must be evident, in accordance with regulations at § 410.32(d)(2) and (3), that the physician ordered the services."

Response: We appreciate the commenters' viewpoint. However, for the reasons discussed previously, we are finalizing our proposal, without modification, to require a physician's or NPP's signature on requisitions for clinical diagnostic laboratory tests paid under the CLFS.

Comment: The commenters suggested that a pre-printed physician signature or letterhead showing the physician's name should serve in the place of a "signature."

Response: A pre-printed signature or letterhead cannot be construed as a document, the contents of which a physician or NPP has affirmed. In order to discourage fraud and abuse, and to affirm that a medical service was ordered by a medical practitioner who currently works in the practice, a signature is required.

Comment: The commenters stated that the services are transcribed from the medical record onto the requisition by office staff, not written and signed by the physician. The commenters seemed to indicate that the medical record that would be maintained in the physician's office, but not necessarily the requisition, would be signed or annotated in some way.

Response: It seems that the commenters believe that a physician or his/her representative has no problem providing a signature or annotation for the medical record. In addition, some commenters consider the "requisition" to be the medical record and use it for a dual purpose—as the beneficiary's file and as the request for services.

After careful consideration of all the comments received, we are finalizing our proposed policy without modification to require a physician's or NPP's signature on requisitions for clinical diagnostic laboratory tests paid under the CLFS. This policy does not affect physicians or NPPs who choose not to use requisitions to request clinical diagnostic laboratory tests paid under the CLFS. Such physicians or NPPs can continue to request such tests by other means, such as by using the annotated medical records, documented telephonic requests, or electronically. We will make changes to our manuals to reflect this final policy.

D. Discussion of Budget Neutrality for the Chiropractic Services Demonstration

Section 651 of MMA requires the Secretary to conduct a demonstration for up to 2-years to evaluate the feasibility and advisability of expanding coverage for chiropractic services under Medicare. Current 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