

applicable, and stated we were “revising § 414.610(c) to reflect that this bonus payment applies only for services furnished during the statutory period.” Thus, in the “Medicare Program; Coverage and Payment of Ambulance Services; Inflation Update for CY 2004” final rule with comment period, we revised the regulation to include the time period during which the adjustment is applicable (68 FR 67963). However, the revised language specifying the statutory time period was dropped inadvertently from the regulation text when § 414.610(c)(5) was later republished in the “Medicare Program; Medicare Ambulance MMA Temporary Rate Increases Beginning July 1, 2004” interim final rule (69 FR 40288, 40292).

In this final rule with comment period, we are finalizing our proposal to reinstate the language that was originally finalized in “Medicare Program; Coverage and Payment of Ambulance Services; Inflation Update for CY 2004” final rule with comment period (68 FR 67963), but then inadvertently omitted again when § 414.610(c)(5) was later republished, so that § 414.610(c)(5)(i) correctly sets forth the statutory time period during which this rural mileage bonus was applicable. This revision to the regulation is a technical correction to conform the regulation to the statute. For further information, see program instruction, Transmittal AB-03-110; Date August 1, 2003; Change Request 2767 which was issued to inform contractors to discontinue paying such bonuses effective January 1, 2004 in accordance with the statute.

M. 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) included 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) 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 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 Clinical Laboratory Fee Schedule (CLFS); however, it must be evident, in accordance with our regulations at § 410.32(d)(2) and (3), that the physician ordered the services. The policy that

signatures are not required on requisitions applies to requisitions for clinical diagnostic laboratory tests paid under the CLFS.

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 lab 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 OPFS), 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). An order may be delivered via 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; or
- 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 labs 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.

The following is summary of the comments we received regarding the discussion of the physician signature on requisitions issue.

Comment: We received several comments concerning the fact that a diagnostic test, such as an x-ray, continues to require the signature of the ordering physician or NPP on the written order whether or not the diagnostic test is paid under the CLFS.

Response: We are appreciative that the general public recognized a clear distinction in the proposed rule between clinical diagnostic laboratory tests paid under the CLFS and diagnostic tests that may also be paid

under the PFS or OPFS. The discussion in the proposed and final rules this year concerns our current policy that a physician's signature is not required on a requisition for clinical diagnostic laboratory tests paid on the basis of the CLFS. This policy was the result of Negotiated Rulemaking and was outlined in proposed and final rules published during 2000 and 2001, respectively (65 FR 13089 and 66 FR 58790, 58801, and 58802). This policy does not include diagnostic tests such as x-rays.

Comment: One commenter was supportive of both policies on which we solicited comments. Specifically, this commenter supported our policy that a written order for diagnostic tests (including those paid under the CLFS and those that are not paid under the CLFS) must be signed by the ordering physician or NPP. The commenter further stated that the request for a diagnostic test represents part of the physician's plan for the patient, which is part of the patient's medical record. As such, when the request is in writing, a physician signature would be appropriate and likely easily generated. The commenter also supported our policy that a physician's signature is not required on a requisition for clinical diagnostic laboratory tests paid on the basis of the CLFS. The commenter stated that, to the extent a requisition is simply a paper mechanism for transmitting an order and more administrative in nature, it is less likely to be generated or handled by the physician. Thus, to require a physician's signature on a requisition for clinical diagnostic laboratory tests paid on the basis of the CLFS would be an added and unnecessary burden on physicians.

Response: We appreciate the commenter's support of our policies and the commenter's input on these issues.

Comment: Several commenters suggested that we should not require a physician's signature on a medical request, whether that request be an order or a requisition, for any type of test, paid under the CLFS or not, within or outside the hospital setting.

Response: To do as commenters suggest would be a departure from long-standing Medicare policy requiring the physician's signature on written orders in other settings. This procedure serves to document that the physician or NPP ordered the test and documented the medical necessity of the test. The exception of not requiring a physician's signature on the requisition for a clinical diagnostic laboratory test paid under the CLFS only is very narrow and does not include other types of tests paid in other types of settings.

Comment: Several commenters raised concerns about issues relating to electronic medical records. Specifically, commenters were concerned whether or not an electronic signature would be acceptable and had questions about what constitutes a medical record in a paperless environment. One commenter stated that, generally, electronic systems that are used to request laboratory testing can be used by physicians with authorized access only and that as a result, a physician's signature should not be expected or required.

Response: We appreciate the commenters' concerns about these issues. CMS is in the process of developing guidelines concerning electronic records and electronic signatures for use in CMS programs. These guidelines will be finalized at a later date. The general public will be kept apprised of our progress on this issue through future official issuances.

Comment: One commenter urged us to establish a "rule of reason" with regard to what is required to be in the medical record, while two other commenters provided detailed suggestions on how to improve our manual language in this regard. These commenters were concerned about the fact that physicians sometimes make shorthand notes or indicate that there was an office visit only without further details in the medical record concerning the specific laboratory tests that are ordered.

Response: We believe that, whenever a physician orders services, including laboratory tests, for a patient in order to assist in diagnosing or treating the patient's conditions, the ordering of those services should be documented in the patient's medical record. Nonetheless, we do appreciate the commenters' concerns about the scope of the medical record and efforts to make detailed suggestions about how to improve the direction provided in our manuals. We will carefully consider these issues and if we decide that further clarification is warranted, will issue such clarification.

Comment: Several commenters were concerned that, while documentation to support an unsigned requisition would be required to be maintained in the medical record, employees at the clinical diagnostic laboratory do not have access to the medical record to verify whether or not this documentation exists. Commenters stated that, once a laboratory receives an order or requisition, it is obligated to perform the test as quickly as possible because it is in the best interest of the Medicare beneficiary, regardless of whether or not a physician signature is

present. Commenters also raised the issue of fragility of the specimen and that it is essential to complete testing as soon as possible before the specimen begins to degrade. Commenters were concerned about being obligated to ensure that orders maintained in the physician's office were signed prior to being able to perform the test in the laboratory. The commenters do not believe that this obligation is fair to them or the Medicare patient as access to essential information could be delayed or compromised. Conversely, another commenter recommended that, in addition to the affirmation by the physician in the medical record that the laboratory test had been ordered, the laboratory should be required to close the loop and provide documentation that the test had been performed for inclusion in the medical record as well.

Response: We recognize that, without the physician's signature on the requisition, some clinical diagnostic laboratories believe it is burdensome to verify that the request for services is valid. However, our regulations at § 410.32(d)(2)(iii) provide the entity submitting the claim (that is, the clinical diagnostic laboratory) with the option to request additional diagnostic and other medical information to document that the services it bills are reasonable and necessary.

Comment: Several commenters believe that the signature issue is burdensome because multiple physician services can be requested on the same form, and, in such cases, one service might require the physician's signature while another might not. For example, it is possible that both the Technical Component (TC) of physician pathology services and clinical laboratory services may appear on the same requisition and that it would be confusing to have one set of requirements for clinical diagnostic laboratory tests and a different set of requirements for physician pathology services. Physicians may not know whether a particular laboratory or pathology test is paid under the CLFS or the PFS. The commenters suggested that we further clarify our policy to address this particular issue. We received a number of comments specifically requesting that we develop a single policy for all outpatient laboratory services, without distinction for those paid under the CLFS or the PFS.

Response: We appreciate the commenters' concerns. We will examine options for creating a fair and consistent policy regarding signatures that will address situational needs.

Comment: Several commenters stated that we needed to draw a clearer

distinction between a requisition and an order, as they did not understand the difference between them. Commenters also suggested that, as medical records move to an electronic format, this distinction becomes more difficult to describe.

Response: We agree with the commenters' interest in having clear and concise distinctions between "requisition" and "order" especially as we move toward electronic means of record keeping and communication. We asked for comments about how to define a requisition, and we did receive some helpful suggestions. At this time, we are not addressing the specific comments on the distinction between orders and requisitions. We will continue to develop clearer direction on this issue, taking into consideration the suggestions submitted by commenters.

Comment: One commenter was concerned that physicians are signing stacks of laboratory requisition forms in advance of their use, or using a pre-signed hand stamp to make a requisition form official. The commenter stated that we did not draw a distinction between requisitions signed in advance and requisitions signed at the point of service for a specific purpose in the presence of the patient.

Response: We appreciate that the commenter brought these real world procedures to our attention. We will review this issue and consider it in the future as we consider all the issues that were brought to our attention through the proposed rulemaking effort this year.

Comment: We received several comments concerning the date of service (DOS) rule in reference to performing clinical diagnostic laboratory tests on stored specimens which were collected from the patient during the time that he/she was an inpatient at a hospital.

Response: We thank the commenters for their concerns on this issue. However, since we have not proposed any changes to the DOS rule at this time, we will not be addressing this comment in this final rule as these comments are outside the scope of our proposals for CY 2010.

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 will continue to carefully consider the issues of physician signatures on requisitions and orders. We plan to revisit these issues in the future paying particular attention to the definition of order and requisition.