ACLA
American
Clinical Laboratory
Association

COMMENTS OF THE AMERICAN CLINICAL LABORATORY ASSOCIATION ON THE MEDICARE PHYSICIAN FEE SCHEDULE PROPOSED RULE FOR CALENDAR YEAR 2011 (CMS-1503-P)

The American Clinical Laboratory Association (ACLA) is pleased to have this opportunity to submit our comments on the Medicare Physician Fee Schedule Proposed Rule for Calendar Year (CY) 2011 ("the Proposed Rule").[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of clinical diagnostic laboratory services to Medicare beneficiaries, ACLA member companies will be directly impacted by the Proposed Rule. ACLA's comments will focus on the following issues: (1) physician signatures on requisitions; (2) disclosure requirements for the in-office ancillary services (IOAS) exception; and (3) the extension of payment for the technical component (TC) of certain physician pathology services.

I. Physician Signatures On Requisitions

In the Proposed Rule, CMS proposes to adopt a major change in the requirements applicable to the ordering of clinical diagnostic laboratory tests. CMS proposes to require that there be a physician or nonphysician practitioner (NPP) signature on requisitions for clinical diagnostic laboratory tests paid on the basis of the Clinical Laboratory Fee Schedule (CLFS). And, based on the proposal, CMS apparently expects to implement this significant policy change on January 1, 2011. CMS makes its proposal without any discussion or recognition of the impact that its proposal would have on clinical laboratories, physicians and, most importantly, Medicare beneficiaries or any acknowledgement that, as its own contractor notes, physicians are still not familiar with the current documentation requirements.

Set forth below, we have discussed our concerns with respect to the proposed policy. We strongly urge CMS to withdraw this proposal and work collaboratively with all of the affected parties to establish a realistic and practical documentation policy that still meets CMS' goal of protecting the Medicare Trust Fund from abuse. Additionally, if finalized, which we strongly advise against, then CMS should delay the implementation of this policy until CMS can educate physicians about these new requirements.

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1 75 *Fed. Reg.* 40040 (July 13, 2010).

A. The 2011 CMS Proposal

In the Proposed Rule, CMS states that it plans to adopt a policy that would require a physician or NPP signature on requisitions for clinical diagnostic laboratory tests paid on the basis of the CLFS. CMS does not specifically address whether a physician's or NPP's signature would be required on a requisition for tests that are paid on the basis of the physician fee schedule, such as physician pathology services. However, based on its discussion of the proposed policy, it appears that CMS plans to require physician signatures on all requisitions and orders regardless of whether the test is paid for on the CLFS or on the physician fee schedule.

CMS states that this policy would be less confusing for everyone because it would eliminate uncertainty over the type of documentation required for a particular type of test. It notes, without any documentation or support, that its proposed policy would not increase the burden on physicians because, according to CMS, physicians are already doing everything that is required anyway. Additionally, CMS states that it is suggesting this change because of the confusion that exists in this area. However, as discussed at length below, much of this confusion appears to be of CMS' own making, as it has attempted to introduce new interpretations of longstanding policies with regard to laboratory test requirements and promulgated new, and increasingly hyper-technical, documentation requirements for all services related to what constitutes a valid physician signature.

While, ACLA appreciates CMS' attempt to create a single policy for requisitions and orders; unfortunately, CMS has taken its policy in the wrong direction. ACLA finds it astounding, given the painstaking efforts made during, and the policies that resulted from, the negotiated rulemaking process, which was mandated by Congress and involved various stakeholders including clinical laboratories, that CMS would take this opportunity to unilaterally and summarily overturn those policies. As set forth by CMS in the Negotiated Rulemaking Final Rule, though a physician's signature is one way of documenting that the treating physician ordered the test, it is not the only permissible way of documenting that a test has been ordered.[2] The current proposal explicitly overturns that policy, and would mandate just the opposite of what it has always required; namely, it would reverse the existing policy so that the *only permissible way* of documenting that a test had been ordered would now be to require a signature.

As discussed below, this policy will only add to the confusion that CMS has created in this area and will simply not work for clinical laboratory services. CMS should establish reasonable requirements that support its actual policy in this area, which is that it must be evident that the physician ordered the laboratory services in accordance with CMS' regulations.[3] We suggest several alternatives to CMS' new proposal to support this rational policy, including making the physician accountable for these requirements, later in our comments.

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2 *Id.* at 40161.

3 *Id.* at 40162.

B. If Confusion Exists In This Area, It Is Confusion CMS Has Created.

The basic rule related to physician signatures on requests for laboratory services was established in 2001, as a result of the negotiated rulemaking process, which brought together representatives of 20 different organizations, representing clinical laboratories, physician groups, consumers, and CMS, itself, to resolve numerous issues related to the ordering and payment of laboratory services. After a year and half of meetings, at which a unanimous consensus was required for each issue, the committee adopted a proposal that physician signatures were not required on laboratory requisitions. As CMS noted at the time, "while 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."[4]

That was the commonly accepted rule until last year, when CMS announced, in the Medicare Physician Fee Schedule Proposed Rule for CY 2010 ("the 2010 Proposed Rule"), that "to resolve any existing confusion surrounding the implementation of the policy in 2001 and subsequent transmittals, [it was] restating and seeking public comments on [its] policy."[5] However, we find it difficult to believe that such confusion existed in the laboratory industry. And, considering that only clinical laboratories were subject to the negotiated rulemaking policy of not requiring physician signatures on laboratory requisitions, any confusion that may have existed among non-laboratory providers of other diagnostic services (*e.g.*, providers of imaging services) should not have warranted CMS' attempt to revisit its policy. Nonetheless, for requisitions, CMS proposed to restate that a physician signature is not required for clinical laboratory diagnostic tests paid on the basis of the CFLS, so long as it is evident that the physician ordered the services in accordance with the existing regulatory requirements relating to documentation and recordkeeping.[6] With respect to an order, which CMS attempted to distinguish from a requisition, CMS stated that its policy had always been that a written order for diagnostic tests including those paid under the CLFS and those that are not paid under the CLFS, such as physician pathology services, must be signed by the ordering physician or NPP. CMS left unresolved whether or not a physician signature would be required on requisitions for laboratory services paid for under the physician fee schedule.

As ACLA pointed out at the time, the 2010 Proposal was not a restatement of CMS' position that was agreed to during the negotiated rulemaking process. Further, there was no support for differing requirements for "requisitions" and "orders" or for there to be any different requirements for clinical laboratory services and anatomical pathology services. For example, the transmittal that CMS cited in the 2010 Proposal, and which it continues to cite in the 2011 Proposed Rule, used the term "order" and "requisition" interchangeably. CMS had never distinguished between how laboratory services were ordered – whether on a requisition or a "script" – in establishing a standard. Nor had CMS historically applied different requirements to tests paid on the basis of the CLFS and those paid on the physician fee schedule. While CMS made the statement last

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4 66 *Fed. Reg.* 58788, 58802 (Nov. 23, 2001) (emphasis added).

5 74 *Fed. Reg.* 33520, 33641 (July 13, 2009).

6 *Id.*

year – and repeats it this year – that after the 2001 Negotiated Rulemaking, it "implicitly" left in place its policy that *orders* for clinical diagnostic laboratory tests had to be signed, that "implicit" requirement would have been a surprise to many in the laboratory industry. After considering all of the comments, however, CMS opted not to make changes last year, but maintained its view of the longstanding policies, and stated it would revisit these issues in the future. CMS has now, again, proposed a change in course that will only help exacerbate the confusion that CMS has, itself, created.

Since the 2010 Final Rule was issued, concern about the appropriate standards has increased. Medicare Administrative Contractors (MACs) and Comprehensive Error Rate Testing (CERT) contractors have increasingly made onerous demands for physician signatures or documentation in a variety of situations. Many of these demands appear to be unnecessary, unreasonable and inconsistent among the various contractors. This is due, in part, to new documentation requirements that have added further confusion and complexity to this area. In March 2010, CMS issued Transmittal 327, "Signature Guidelines for Medical Review Purposes," that establishes requirements for how contractors are to verify a handwritten and electronic signature, including instances where a handwritten signature is "illegible."[7] It sets forth new procedures, including a signature log and a signature attestation statement, as methods of verifying unclear or illegible signatures. It also provides, however, that signatures are not required for clinical laboratory orders, although for the first time, to our knowledge, it required the physician to authenticate his or her intent to order tests by signing the medical record or progress note.

In light of all of these changes, it appears that even CMS' own contractors are having trouble keeping up with, and implementing, the requirements in this area. Our laboratories recently received a letter dated July 14, 2010 from CIGNA Government Services (CIGNA) asking for help from providers in educating physicians about Medicare documentation requirements.[8] The letter seeks support in educating physicians on these requirements, especially with regard to problems with valid signatures and missing orders for services billed to Medicare. CIGNA reports CERT error rates in this area are increasing "at an alarming rate." While it states that it is attempting to educate physicians about the requirements, CIGNA notes "this is a slow and labor-intensive process, and is especially difficult for us [i.e. CIGNA] to reach the actual physicians." Most significantly, the CIGNA letter states, "This situation represents 'low hanging fruit' to [Recovery Audit Contractors (RACs)] and could result in large provider groups having to repay hundreds of thousands to millions of dollars in incorrectly paid monies for improperly documented or billed services. Even a successful defense process can be costly in time and resources."

In sum, there is confusion with respect to the rules in this area because CMS keeps "clarifying" them and adding to them. It issues new requirements for determining when a signature is valid and then its contractors warn that providers will be "low hanging fruit"

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[7] *See* Transmittal 327, Change Request 6698, "Signature Guidelines for Medical Review Purposes" (March 16, 2010) ("Transmittal 327").

[8] *See* Cigna Government Services Letter to Compliance Officers, dated July 14, 2010.

for RAC audits when these requirements cannot be met. This cycle of confusion is a sign that CMS should review its policies in this area and establish policies that are more practical, sensible, and easy to follow. We suggest that CMS return to the true question here – Is it evident from the record that the physician actually ordered the laboratory service in question?

C. Physician Signatures Should Not Be Required On Laboratory Requisitions Or On Laboratory Orders.

As we stated in our comments to the 2010 Proposed Rule, a physician signature should not be required on a requisition or an order for laboratory tests regardless of how the test is reimbursed. A policy that provides otherwise would be inherently flawed and would have significant consequences for clinical laboratories.

Physicians do not (and will not) sign requisitions. The greatest obstacle here is that physicians do not sign laboratory requisitions. This was the reason that the Negotiated Rulemaking Final Rule eliminated the requirement in 2001. Laboratory requisitions usually include an extensive list of different test services offered by the laboratory. Because of the number and breadth of services offered and because the patient typically does not go to the laboratory in person, these documents are often quite detailed, requiring a variety of demographic, billing, and clinical information that have to be included. Given the time constraints and pressures on physicians, they are unlikely to fill out the requisition themselves, but rather give directions to a nurse or other individual concerning what is required and then leave it to that individual to actually complete the requisition. The physician will then either dictate his notes for the medical record or make a handwritten note in the record, which he may initial or sign off on. Theoretically, it would be possible to have the physician actually sign the requisition after someone else has filled it out, but that seems like unnecessary "paper pushing." As one commenter put it last year, "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."[9]

Laboratories have no way to enforce the physician signature requirement. CMS is attempting to impose requirements on laboratories that they have no ability to enforce.[10] Laboratories cannot ensure that orders are signed by physicians prior to furnishing the laboratory service because we are indirect providers of care. Once a laboratory receives an order or requisition with a specimen, the laboratory feels 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. In addition, due to the fragility of the specimen, if testing is not completed shortly after receipt, the

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9 74 *Fed. Reg.* 61738, 61930 (Nov. 25, 2009).

10 Although it has been suggested that laboratories could sue physicians for failing to comply with the proposed signature requirement, there is no legal basis on which to bring such a suit, particularly if CMS fails to enforce its own requirement on physicians.

specimen will begin to degrade. Requiring physician signatures on laboratory requisitions or orders only puts the laboratory in the untenable position of either having to delay providing the service while it follows-up with the physician to obtain a signature or providing the service but not being able to bill for it. Such a choice might be acceptable if it occurred infrequently, but laboratories perform tens of thousands of tests each day, which will make it impossible to follow up on every missing and illegible signature. This is further complicated by the fact that Medicare would be one of few payers to require a physician signature on a requisition, which would require laboratories to sift through requisitions to distinguish among payers to ensure that Medicare requisitions were appropriately signed or to request a physician's signature on all requisitions, regardless of the payer. Either of these alternatives would present undue burdens on the laboratory.

Laboratories' inability to enforce this policy as an indirect provider is even more pronounced in the nursing home setting. In most nursing homes, the physician often will request laboratory tests after speaking with a nurse at the facility; however, it is the nurse who actually places the order with the laboratory. Depending on state law, physicians are only required to be in the facility once every 30 to 45 days. As such, this policy would present significant issues for laboratories that service nursing homes because in most instances the nurse would be filling an order that has not been signed by the physician until days or weeks later. Because laboratories that service nursing homes would be forced to operate under the confines of each state's laws, these laboratories would be uniquely at risk for audits by Medicare contractors through no fault of their own.

The policy would injure beneficiaries. This policy would result in a delay of care to Medicare beneficiaries. For example, under the proposed policy, a patient that visits a patient service center (PSC) with an unsigned requisition (or order) for scheduled testing after eight hours of fasting may be asked to return to their treating physician to obtain the required signatures on their requisition (or order). This patient may be turned away, even if the patient's medical record is properly documented because neither the patient nor the laboratory would be likely to know this at the time the patient visits the PSC. While the PSC would be reluctant to turn the patient away, laboratories will, again, be put in the untenable position of either providing the requested testing and risk not being reimbursed for the services provided or asking the beneficiary to return with a signed requisition (or order). This cannot be a result that CMS envisioned and, the impact on beneficiary care alone is sufficient reason for CMS to revise its proposed policy.

CMS policy would create undue burdens on laboratories and physicians. CMS' proposed policy would be unduly burdensome on laboratories for many of the reasons already discussed, but also because laboratories would be required to expend additional time and resources to track down physicians in an attempt to obtain signatures for unsigned requisitions and orders. Without an ability to enforce the proposed physician signature policy, laboratories would be forced to attempt to contact physicians whenever a signature is missing from a requisition or order to ensure payment, which could happen frequently. Additionally, even if the requisition were signed, in many instances the signature would be illegible. Based on Transmittal 327, it appears that laboratories would then be required to obtain a "signature attestation statement" or "signature log" from physicians in order to verify that the test was, in fact, ordered by the physician.

This would result in more paper going back and forth between physicians and laboratories, increased costs for all parties, and additional frustration.

Requiring a physician signature for the ordering of laboratory services on an order or requisition would not address the fraud and abuse concerns that CMS seems to want to address here. We understand that Medicare does not want to pay for services that are not properly ordered. However, at the same time, CMS should not institute unreasonable policies that have no purpose other than penalizing providers. When a physician orders a laboratory test, he must draw a specimen from the patient (or send the patient to a PSC), which is then sent to the laboratory. The tests ordered will be shown on the requisition, which will have the patient's name and identifying information on it, as well as information concerning the ordering physician. In addition, the medical record will contain information about the patient's history, and the physician's notes related to that patient encounter. The laboratory will then send results back to the physician, which will be reflected in the medical record. All of this documentation should be more than enough to allow a judgment about whether or not the physician saw the patient and ordered the services. The addition of a signature—and the new cumbersome process to authenticate that signature—does not really appear to add a great deal of value with respect to whether or not a laboratory service is legitimately ordered by the physician.

We understand that CMS is concerned about situations where unscrupulous providers conspire with physicians and/or patients to bill for services that were not performed or ordered. Such activities are clearly improper. But, if the participants are engaging in this level of improper activity, it is not clear what additional protection obtaining a signature will afford. To impose burdensome physician signature requirements for the ordering of laboratory services does little to minimize the risk of the rare renegade performing unnecessary testing. Further, since auditors always request the medical record anyway to determine medical necessity, it is not clear that requiring a physician signature will ultimately reduce the documentation or burdens on the laboratory or the physician.

While contractors trumpet that CERT contractors are finding errors increasing "at an alarming rate," we are somewhat skeptical that this is a result of increased abusive activity. We expect an analysis would show that virtually all of those services were appropriate for the patient and were, in fact, ordered by the physician. In fact, in the vast majority of these situations, the error is not that the service is not documented, but that an auditor has been able to find some highly technical way to question the order, such as whether the signature is sufficiently "legible" – a highly subjective determination. As a result, we question whether the proposed policy and additional new requirements will really help prevent abuse, or whether they will simply impose new, unreasonable obstacles, to a provider's ability to be paid for their services.

This will result in increased burdens to physicians. CMS notes in the Proposed Rule that its proposed policy should result in no increased burden to physicians because physicians regularly annotate the patient's medical record with either a signature or an initial, which CMS refers to as the "order" and provide signatures on the paperwork

provided to the laboratory, which CMS refers to as the "requisition."[11] We find this assertion by CMS surprising, however, because if physicians regularly signed requisitions for laboratory services this discussion relating to the requirements for a valid laboratory order and the need for CMS to clarify its policies would be moot. As noted above, members of the laboratory industry would argue that CMS' assertion that physicians regularly sign "requisitions" is incorrect and is actually the opposite of what occurs in most instances. We are very interested in, and would welcome the opportunity to, review the data that CMS used to determine that in most instances physicians sign requisitions for laboratory testing. In fact, we note that while CMS states it does not expect that this change will be burdensome, it does not make any burden assessment in the Regulatory Impact Statement of the Proposed Rule, as arguably it is required to do. If it has data to support this statement, then it should have included it in the Proposed Rule. If it does not, then it is hard to see what basis it has for a statement that seems clearly contradicted by the facts.

D. CMS Should Develop Clear, Reasonable Documentation Policies For Laboratory Tests.

Given the above and the current environment, in which all providers are subject to potential audits from Medicare contractors, laboratories are justifiably concerned about CMS' documentation policies. Thus, instead of adding confusion to the already unclear policies and continuing to propose policies that are unenforceable as a practical matter, CMS needs to develop clear, reasonable requirements with respect to physician signatures. We have provided below our view of what those policies should include.

1. Electronic Orders

An overwhelming majority of laboratory orders are now made on an electronic basis. Therefore, it is critical that CMS set forth clear policies with respect to electronic orders. In fact, it has been the experience of our member laboratories that Medicare contractors have questions as to what the requirements are with respect to electronic orders and signatures.

To this end, we recommend that if laboratory testing is ordered electronically, so long as the laboratory is able to demonstrate that there is a system in place that permits only physicians or other authorized persons with secure access (*e.g.*, password protected) to request laboratory testing or that the testing is ordered through a "certified EHR technology" or a certified "EHR Module," as these terms are defined by the Office of the National Coordinator (ONC),[12] there should be no physician signature required for the electronic order. For example, an electronic physician signature should not be required when a physician places an order on their own certified EHR system or a laboratory's secure system after logging in and using some type of unique identifier or password. Additionally, if laboratory testing is ordered through a secured system then there should be no request by Medicare contractors for the laboratory to produce a hardcopy signature

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11 75 *Fed. Reg.* at 40162-63.

12 75 *Fed. Reg.* 44590, 44595-7 (July 28, 2010).

by the physician as evidence of the order as CMS permits for the ordering of Part B drugs through a qualified e-prescribing system.[13] In instances where laboratory orders are made electronically through secured electronic systems, the risk of an unauthorized person placing an order is minimal at best and, therefore, just does not warrant the need for an electronic signature.

Lastly, we note that Transmittal 327 includes a short statement regarding electronic signatures, but does not provide much insight into what CMS believes should be required with respect to laboratory orders.[14] Therefore, we believe that CMS should use this opportunity to clarify what it will require for laboratory orders as well.

2. *Paper Requisitions and Orders*

With respect to paper requisitions and orders, we would make the following recommendations. First, we again urge CMS not to institute a physician signature requirement, for all of the reasons stated above. We believe this rule should apply to all laboratory services, both clinical and anatomic pathology services, regardless of whether they are requested on a "requisition" or on "order." We believe that the physician's intent to request laboratory services should be reflected in the patient's medical record, which should be initialed or signed.

Second, there is a need for both clarity and practicality with respect to the way in which the medical record should be documented. As such, we urge CMS to adopt a "rule of reason" with regard to what is required to be in the medical record, as well as its policies as a whole. It is our recommendation that the medical record be annotated with either a signature or initials of the ordering physician. If the medical record is initialed, there should be some type of signature log at the facility or physician's office that would include the physician's printed name, signed name, and initials. The physician's annotation should be permitted to be anywhere in the medical record on the date the test was ordered and, not necessarily beside the ordered test. For example, if the medical record demonstrates that the physician saw the beneficiary on the day the test was ordered, there is documentation that laboratory services were ordered, and the laboratory can provide a requisition or order for those services, there should be a presumption that the physician, in fact, requested the services.

Third, our member laboratories have raised issues with respect to the level of specificity of an ordered test on the requisition versus that which is documented in the medical record. There have been instances where Medicare contractors have questioned medical necessity and requested supporting documentation when, for example, a physician has ordered a "complete blood count (CBC) with differential" on a requisition, but only "CBC" is noted in the medical record. While we of course appreciate the difference between the two tests, if the test with the greater level of specificity is

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[13] In the context of prescribing Part B drugs electronically, CMS states that "[w]hen Part B drugs are ordered through a qualified e-prescribing system, the review shall NOT require the provider to produce hardcopy pen and ink signatures as evidence of a drug order." *See* Transmittal 327.

[14] *See id.*

deliberately ordered or selected on the requisition (*i.e.*, the requisition lists both CBC and CBC with differential and allows the physician to select either test), it is unreasonable to assume that the physician did so in error, particularly if both tests were listed. The more logical assumption would be that the physician ordered the medically necessary test on the requisition and used shorthand in the medical record to identify the same test. Therefore, we would recommend that CMS follow this approach. If the test ordered on the requisition is a greater level of specificity than the more general test noted in the medical record, the laboratory should be permitted to furnish, and be paid for, the test listed on the requisition without having to provide supporting documentation in support of the testing of higher specificity.

E. Physicians Should Be Held Equally Accountable For Billing And Reimbursement Policies.

Notwithstanding our comments above, if CMS intends to finalize a policy that would require physicians to sign all orders and requisitions, CMS must find a way to incentivize physicians to change their current behavior. As discussed earlier, laboratories have no way to enforce physician documentation requirements on orders and requisitions, yet only the laboratory is being penalized by having its payments denied or facing the laborious task of having to contact the physician to obtain medical records or other supporting documentation to prove the order was valid and is medically necessary.

If CMS wants to change physician behavior, the onus must also be on the physician. One approach is to tie the physician's payment to the physician documentation requirements. For any given encounter with a physician, he or she almost always bills for an evaluation and management service ("E/M service"). As part of the E/M service there are certain medical documentation requirements that are tied to the physician's payments depending on the type of service. For example, the 1997 Documentation Guidelines provide that "[i]f a diagnostic test or procedure is ordered, planned, scheduled, or performed at the time of the E/M encounter, the type of service, eg, lab or e-ray, should be documented."[15]

Similarly, if CMS intends to require physician signatures on requisitions and orders or require other documentation, the physician should not be permitted to bill for the office visit unless the physician satisfies those requirements. If the failure to include a physician signature on a laboratory requisition or order renders the requisition or order invalid for purposes of the laboratory billing for the service, then the physician's claim should also be denied because he or she has not performed the necessary components of his or her service. Importantly, we are not recommending a policy that would penalize physicians for something for which laboratories are responsible. On the contrary, physicians would be penalized for their own failure to comply with the billing requirements. We believe this approach would level the playing field and incentivize physicians to comply with CMS' proposed policy, if finalized.

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[15] *See* 1997 Documentation Guidelines for Evaluation and Management Services.

F. If Finalized, CMS Should Delay The Implementation Of Its Proposed Physician Signature Policy.

As a final point, but an important one, should CMS finalize the proposed policy, we encourage CMS to delay its implementation. Over the years, through our experience with physicians as CMS has both modified and adopted new Medicare billing and reimbursement policies, we have become keenly aware of the difficulties that are inherent to making these types of changes. Although CMS puts forth its guidance and educational materials to get providers up to speed on new policies, in most instances it is the laboratory itself that is ultimately left with the task of educating physicians on Medicare billing and reimbursement changes with respect to laboratory services. This was the case with the transition to the new Advance Beneficiary Notice of Noncoverage (ABN) and will be the case with the implementation of the International Classification of Diseases, 10th Revision (ICD-10).

Again, as noted by CIGNA, these types of educational efforts are "slow and labor-intensive" processes and it is often particularly difficult to get physicians on board.[16] As such, even CMS' own contractors acknowledge the difficulties in ensuring that physicians are aware and educated about Medicare policy changes. And, despite the fact the CMS is under the mistaken belief that in most instances requisitions and orders are signed, this is not at all the case. In addition, there would be significant financial costs to the laboratory as well. Therefore, it would be an uphill battle to facilitate physician's compliance with the proposed policy, which would need to be phased-in over time. Thus, if finalized, we strongly urge CMS to allow laboratories and physicians a substantial grace period before CMS implements the proposed policy. Ideally, this delay would allow laboratories and physicians the opportunity to adjust to the new physician signature policy, if finalized, and to determine how best to comply.

II. Disclosure Requirements For The IOAS Exception

ACLA is very concerned that CMS has again failed to include any proposals in the Proposed Rule to address its longstanding concern about potentially abusive anatomic pathology self-referral arrangements. As noted by both CMS and the Medicare Payment Advisory Commission (MedPAC), these arrangements pose a high risk for abuse as they allow physicians to profit from their referrals of anatomic pathology services, which incentivizes increased volume. ACLA encourages CMS, at a minimum, to restate and emphasize its concerns about these arrangements in the final rule so as to deter such arrangements in 2011. In addition, CMS should work with ACLA and other laboratory associations to amend the Medicare regulations in order to permanently end these abusive arrangements.

As we have discussed with CMS staff on a number of occasions over the last few years, physician specialists are increasingly taking advantage of gaps in the anti-markup and self-referral rules, and entering into business arrangements that permit them to order, bill and be paid the full fee schedule rate for anatomic pathology services, even though

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16 *See* Cigna Government Services Letter to Compliance Officers, dated July 14, 2010.

the services are actually furnished by physicians who have little or no relationship with the ordering physician and his or her group. The IOAS exception allows a physician or group practice to self-refer and bill for anatomic pathology services that are performed in the physician's office or space in the same building or a centralized building, as defined in 42 C.F.R. § 411.355. Most non-pathology physician practices that bill for anatomic pathology services take advantage of the IOAS exception to comply with Stark.

In the 2008 Medicare Physician Fee Schedule Proposed Rule (the "2008 Proposed Rule"), CMS stated its concern that "...allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic testing services and to then realize a profit when billing Medicare may lead to patient and program abuse in the form of overutilization of services and result in higher costs to the Medicare Program."[17] MedPAC has recently expressed similar concerns in its Report to the Congress, stating:

> The Commission has also noted the rapid growth of services covered by the IOAS exception and evidence that these services are sometimes furnished inappropriately. Physician self-referral of ancillary services creates incentives to increase volume under Medicare's current fee-for-service (FFS) payment systems, which reward higher volume.[18]

CMS declined to issue a specific proposal in the 2008 Proposed Rule for amending the IOAS exception[19] and instead attempted to address the problem of anatomic pathology self-referral arrangements by way of the anti-markup rule. However, the changes to the anti-markup rule that became effective January 1, 2009 in fact only served to exacerbate the problem, as it essentially exempted anatomic pathology services from the anti-markup restrictions.

Under the current anti-markup rule, there is virtually nothing to prevent a physician from marking up an anatomic pathology service that he does not perform. Under the rule, a billing physician may mark up the TC or professional component (PC) of a diagnostic test if the performing physician or supplier "shares a practice" with the billing physician. A shared practice may be found if (1) the performing physician furnishes at least 75 percent of his services through the billing physician; or (2) the test (or component) is performed in the office of the billing physician. For purposes of the PC, this restriction poses little difficulty for most practices, because the performing physician need not be a group member at all, but only needs to perform the service on-site in order to permit the group practice to mark it up. This minimal relationship related to where the service is performed should not be considered "sharing a practice" for purposes of the anti-markup rule, and CMS should eliminate this site of service provision.

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17 72 *Fed. Reg.* 38122, 38179 (July 12, 2007).

18 MedPAC, "Report to the Congress: Aligning Incentives in Medicare," p. 217 (June 2010).

19 *See* 72 *Fed. Reg.* at 38181.

For purposes of the TC, the performing physician is the physician who supervises the TC. However, as CMS has stated that there is no supervision requirement for the TC of anatomic pathology services, the billing physician or group is therefore unrestricted in its ability to mark up the TC. As we have pointed out in the past, it is contrary to logic and public policy that Medicare imposes no supervision requirements on such a vital health care service, typically involving the diagnosis of cancer or other diseases. Finally, CMS in the 2009 anti-markup rule removed all references to "purchased tests," thereby eliminating a longstanding rule that prevented physicians from marking up tests they purchased from an outside supplier.

Thus, the IOAS exception permits a physician group to self-refer and bill for anatomic pathology services performed in the physician's office or space in the same building or a centralized building, and the anti-markup rule imposes no restriction on the group's ability to mark up the service to the full fee schedule rate. As a result of CMS' current interpretation and the agency's silence on the issue since 2008, anatomic pathology self-referral arrangements have exploded. We have seen dozens of examples, including direct advertising materials sent to physicians, medical specialty newsletters and displays at conferences, touting in-house labs and contract arrangements as legal ways to profit from anatomic pathology services. We have also seen evidence that these arrangements are bound to proliferate even further in the coming years if CMS does not address the issue this year. For example, one consulting group wrote last year after the 2010 Physician Fee Schedule Proposed Rule was issued: "What about new regulations? In July, CMS issued their proposed regulations for 2010. They contain nothing restricting or eliminating these ancillary services."

ACLA urges CMS to include a discussion of abusive self-referral arrangements and the IOAS exception in the 2011 final rule as a deterrent to physician groups that are considering entering into such arrangements and as a signal to those currently involved in such arrangements that CMS is preparing to take action. Each year that CMS remains silent on this issue functions as a "green light" for these arrangements to continue. We wish to continue to work with CMS to amend the Medicare regulations—whether the IOAS exception, the anti-markup rule or another section—to curtail these abuses for the protection of the Medicare program and Medicare beneficiaries.

III. Extension Of Payment For The TC Of Certain Physician Pathology Services

Section 3104 of the Affordable Care Act (ACA) continues payments to independent laboratories for the TC of physician pathology services for FFS Medicare beneficiaries who are inpatients or outpatients of a covered hospital through CY 2010. In implementing this provision, the Proposed Rule revises 42 C.F.R. § 415.130(d) to reflect that for services furnished prior to December 31, 2010, an independent laboratory may bill the Medicare contractor for the TC of physician pathology services furnished to a hospital inpatient or outpatient. For services furnished after December 31, 2010, an independent laboratory may not bill the Medicare contractor for such services furnished to a hospital inpatient or outpatient.

ACLA, again, requests that CMS implement the grandfather provision on a permanent basis, as we do not believe the TC is already included in either the diagnosis-related group or hospital outpatient prospective payment system payment made to the hospital for the service. Implementing the provision on a permanent basis would also eliminate the billing issues that occur each time the provision is set to expire.

Thank you for the opportunity to comment. If you have any questions or need any further information, please do not hesitate to contact JoAnne Glisson at (202) 637-9466 or glisson@clinical-labs.org.