Questions from the Clinical Laboratory Coalition for CMS
Regarding Physician Signature Issue

Justification

1. Why does CMS feel this additional requirement is necessary? What is the basis for requiring the physician's signature on the laboratory requisition when information documented in the patient chart already demonstrates that the test was intended to be ordered by the physician?
2. Why did CMS feel the need to change the decision made during a community wide negotiated rulemaking process?
3. What is the fraudulent or abusive activity that the physician signature rule is intended to address? Who is engaging in such activity? How frequently does it occur? Where is it occurring?
4. What behavior will the physician signature rule prohibit or deter that is not already prohibited or deterred by State and Federal false claim acts?
5. What is the public policy justification for penalizing laboratories for the failure or refusal of physicians to sign test requisitions, when laboratories have no control over physician behavior?
6. Did CMS consider incentivizing physicians to sign laboratory test requisitions rather than penalizing laboratories when physicians fail or refuse to sign them? If not, why not? If so, why were physician incentives rejected? What incentive does a physician have to sign a test requisition when it is the laboratory, not the physician, who will suffer if it is not signed, the physician receives no benefit by signing it, and the physician must make significant workflow changes to accommodate the request?
7. How does the physician signature rule promote the President's goal of job creation, when the rule will result in significant revenue losses for most laboratories?
8. How does the physician signature rule promote the health of Medicare beneficiaries when it will result in the delay or denial of medically necessary laboratory testing?

Logistics

1. What is CMS' definition of a requisition? Is this just terminology used to define the paper? What if the paper that accompanied the specimen was called something different?
2. Does the signature need to be collected at the time of the order, or could one go back to collect a missing signature after the fact?
3. Many carriers are telling labs different things about the signature requirement, for example, some are still saying they are not required as a result of the communication that came out over the summer regarding the CERT audits in which it clearly states that clinical labs are an exception to the signature on requisition requirement. How are we to be sure that labs are getting the right information from carriers?
4. What should the laboratory do if it has a current CERT denial for an illegible signature on a requisition since a signature is not, at least at this time, required?

5. What is the CMS definition of a electronic order? How would the laboratory document an "electronic order?"
6. We understand that electronic orders are exempt, however, when an electronic order is sent to a laboratory a piece of paper is generated in the lab to accompany the specimen through the testing process. This paper is called a requisition. The doctor never sees this paper, does it need to be signed? If so, how is the lab supposed to collect that signature?
7. When a physician enters a test order electronically into his electronic health record (EHR) system, but the EHR is not interfaced with the laboratory and the test order is not electronically transmitted to the laboratory, must the physician sign the paper requisition or manifest that the physician prints out to be sent to the laboratory with the specimen?
8. In the case of requisitions for standing orders, do each of the recurring testing scenarios need to have a separate signed requisition or will the signed initial requisition that sets up the standing order be sufficient?
9. If a requisition is faxed to a laboratory, is that an electronic order or does the requisition have to be signed by the ordering physician?
10. In the case of a computer system that allows electronic signatures, would a paper requisition that includes the term "signed electronically by" be considered a signed requisition for the purposes of this requirement?
11. If the laboratory receives an unsigned requisition and then calls the ordering physician to verify the order by telephone, would the telephone confirmation then be considered a "telephonic order" and be documented as such with the original unsigned requisition?
12. Would the laboratory be subject to the same signature legibility requirements as other providers? If that is the case, if there is an illegible signature on a requisition where the physician's name is printed, would that suffice to meet the legibility requirements?
13. What are the consequences for a laboratory who submits a claim based on an unsigned requisition, if, subsequently it is determined that a valid order exists in the patient's medical record or has been signed by the physician? Would this be considered a valid claim, a false claim? Would the laboratory still be required to refund the payment?
14. In the case of a pathologist adding an order for a special stain when performing a tissue exam, would the original ordering physician have to sign that order or would the pathologist signature suffice?
15. Would it be acceptable for documentation of the validity of the order, and meet the conditions of coverage, if the laboratory obtains a signature on a faxed or scanned copy of the requisitions, a faxed or scanned authorization, hard copy documentation of a telephone contact with the physician; a trailer (listing of patients for that physician missing signatures), an e-mail or some other document?
16. If the ordering provider is different from the billing provider whose signature is required? This is often the case for house staff/residence who can legally place orders but who are not the billing provider for the test.
17. What documentation on a paper requisition will be deemed adequate to demonstrate that a test order was communicated by telephone?

18. If a physician or NPP signature is not on the requisition and the ordering physician does not have the ability to submit a revised requisition with signature, will telephone approval be accepted with notation of the call, especially for time sensitive and irreplaceable specimens?

19. When an unsigned test requisition is identified, may another ordering physician in that practice sign on behalf of the original ordering provider when the original ordering physician is not available, such as when the doctor is at the nursing home, at the hospital, left for the day, or is on vacation?

20. What if the physician office general policy/procedure indicates that the office manager or other designee can sign the requisition vs. the physician? How should this be addressed?

21. Must the physician signature block on the test requisition state "Physician Signature", or will the following examples be acceptable: 1) Physician/Designee Signature, 2) Medical Practitioner, 3) Authorized Signature, or 4) Physician/Authorized Signature?

22. When a reference laboratory receives a test order electronically or on paper from a referring laboratory without the original physician test order, whether the original physician test order was electronic or manual, is the reference laboratory permitted to bill Medicare for the test without a signed test requisition from the ordering physician?

23. What if the laboratory receives BOTH the electronic order from the physician's EHR and a printed unsigned requisition that accompanies the laboratory specimen – can the laboratory rely on the electronic order or must it still obtain a signature on the requisition?

24. Which laboratory is responsible for claims submitted in the absence of a physician signature on the original test requisition, when the order is an electronic lab-to-lab order and the reference laboratory submits the claim?

25. Is an electronic order from one lab to another lab (lab to lab referral) considered to be an electronic order that does not need a physician signature? What if the original requisition did not have a physician's signature?

26. Will CMS clarify what constitutes a valid signature on the requisition, bearing in mind that the chart or other patient medical records are required to contain documentation of the orders by the physician or other authorized party? Will CMS include this clarification in its physician education and training activities?

27. Is it permissible for a physician to provide a one-time blanket authorization/signature that would satisfy the requirement for each and every Medicare paper requisition sent to the laboratory (ie, a signature on file)?

28. If a physician signs a stack of blank test requisition forms which are subsequently submitted to a laboratory with test orders, and the laboratory performs the tests and bills Medicare, has there been a violation of the physician signature requirement? If so, which party or parties have violated the requirement? Who will be punished? How would a laboratory know whether or not the requisitions had been signed when they were blank?

29. Does this requirement apply to laboratory tests paid on the basis of the physician fee schedule?

30. A laboratory performs the Technical Component ("TC") of an anatomic pathology test for a grandfathered hospital. The hospital sends a manifest which lists the accession number of each specimen that accompanies the manifest. The laboratory performs the TC on each specimen and bills Medicare for each TC. The laboratory retains a copy of the manifest. Does the laboratory have to have a requisition that is signed by the ordering physician for each TC?

Impact on Patient Care

1. What safeguards will CMS establish to ensure that patient care will not be negatively impacted for lack of a physician's or NPP's signature on a requisition?
2. Other than education, what steps will CMS take to ensure that physicians and non-physician practitioners sign laboratory test requisitions so that patient care will not be delayed or denied?
3. When a specimen is collected from a home bound patient the doctor is not on sight. In many cases a lab tests for a home bound patient is extremely time sensitive. How can the laboratory collect the signature to ensure timely testing?
4. When a physician practice collects a patient's specimen rather than utilizing a laboratory's patient service center, and the specimen pick-up is scheduled after office hours, should the lab personnel leave the specimen at the physician's office if the test order does not contain a physician signature? If the specimen should be picked up, when the specimen arrives at the laboratory, should testing be delayed while the physician signature is obtained? If the specimen should be tested, should transmission of the test result back to the physician be delayed while the physician signature is obtained?
5. Should laboratories discontinue requested after-hours specimen pickup services for physician practices, or should the physician remain in the office after hours to ensure that all test requisitions have been signed when the specimens are picked up?
6. Are STAT laboratory orders exempt from the physician signature requirement, or should these critical care services be delayed while an attempt is made to obtain the physician's signature?
7. If a physician or NPP signature is not received prior to testing, would CMS direct laboratories not to proceed with testing?
8. Are laboratories free to refuse service to patients that present at the patient service center when their test requisition does not contain a physician or NPP signature? Will CMS education materials include this guidance for both physicians and patients? When we educate patients regarding this requirement, who is the individual at CMS to whom we should direct patients for further inquiries?
9. Assuming a test requisition is signed by the ordering physician, if initial testing could not be performed and a redraw or recollection is required, such as where the quantity of the specimen was not sufficient, will the ordering physician's signature be required again, or will the signature on the original requisition be sufficient?

10. Services to beneficiaries may be delayed or denied as a consequence of the new requirement. Has CMS considered the adverse impact on the beneficiary's access to services?
11. Is a physician signature required for Medicare beneficiaries enrolled in Medicare Advantage programs?
12. If a patient's Medicare coverage is secondary, is a physician or NPP signature required on a test requisition?
13. Does the physician signature rule apply to tests ordered for Medicaid beneficiaries?
14. Does the physician signature rule apply to tests ordered for beneficiaries of Private Insurance or Medicare and Medicaid managed care plans?
15. If the laboratory performs testing without a signed requisition, is the laboratory under any obligation to provide results to a patient's PHR?
16. Does the signature requirement apply when Medicare is the secondary payer?
17. What if the unsigned requisition comes in as a non-Medicare requisition, but it turns out that Medicare is the primary payer?

Payment Issues

1. If a clinical laboratory performs a test ordered by a physician and results are provided, but the performing laboratory cannot bill Medicare due to the failure or refusal of the physician to sign the test requisition, how can the performing laboratory recoup the cost of the test? May clinical laboratories bill the ordering physician?
2. If a patient presents a test requisition at Patient Service Center (PSC) without a physician signature, may a patient elect to be financially responsible for payment?
3. Could a physician signature on a requisition support the legitimacy of the laboratory claim in a post-payment audit, even if the laboratory order was not entered or signed in the patient's chart or medical record?
4. What does CMS estimate the cost to physicians, laboratories, and beneficiaries will be as a result of the changes?
5. Would CMS consider providing financial or other incentives to physicians to sign requisitions and / or penalties for physicians that repeatedly fail to provide laboratories with signatures (similar to the meaningful use incentives / penalties)?
6. Would CMS consider penalizing physicians for failing to sign laboratory requisitions as they are required to do for pharmaceuticals?
7. Assuming the orders are documented in the chart or other patient medical record, is it considered to be a false claim if a laboratory were to submit a claim when the requisition was not signed?

8. Should a laboratory submit a claim at the insistence of the beneficiary that is seeking a denial for purposes of secondary coverage, even if the requisition was not signed or may the laboratory refuse the beneficiary's request?

9. If a laboratory performs testing when the requisition does not have a signature, but does not submit a claim to Medicare for testing, is the order valid for CLIA purposes or should the laboratory refuse to perform the tests and refuse to collect the specimens or return the specimens to the physician?

10. If physician signature is a condition of coverage, can the laboratory get an ABN from the beneficiary making the service the financial responsibility of the beneficiary? Can the laboratory bill the beneficiary without an ABN?

11. If clients refuse to provide signatures on Medicare beneficiary requisitions despite education and training and the laboratory performs testing to protect the beneficiary, is the laboratory's failure to bill anyone (including the physician) contrary to the anti-kickback law?

12. Should the laboratory bill the physician in that case? If yes, would CMS provide that guidance in its educational materials for physicians?

13. If we are able to obtain the ordering provider signature after the fact, do we have to obtain the specific ordering provider signature or can another provider in the same group practice sign?

14. Most labs have gone paperless as far as record retention/storage is concerned. In an audit, the laboratory may not be able to produce the actual original paper requisition but an exact image of the requisition. If the auditor were unable to tell if the physician signature were hand-written or stamped, would that invalidate the signature?

15. All licensed LTC facilities are inspected by state auditors once a year. One of the inspection checks is whether lab tests in patient charts are signed by the physician. Results of those inspections are forwarded to CMS and published by OIG. Isn't requiring an additional signature on the requisition redundant?

Education

1. When will the CMS educational effort begin? How long will it last?
2. To whom is the CMS educational effort being directed? Physicians? Office staff? Patients? Nursing Homes? Home Health Care? Phlebotomists? Laboratory Operations Personnel? Laboratory Billing Personnel? Health IT vendors?
3. What methodologies will CMS use to educate the intended audience about the physician signature rule other than passive methodologies such as postings on its website, webinars, and teleconferences which hundreds of thousands of affected physicians and other stakeholders will never take advantage of?

4. How will CMS assess the effectiveness of its educational effort? What criteria will CMS use to determine whether or not the effort has been successful? What will CMS do if its educational effort is not successful?

Special Concerns for Skilled Nursing Facilities

The skilled nursing facility (SNF) community is gravely concerned about the potential harmful impact of this new requirement on the 1.5 million patients we serve daily and the over 2.8 million served annually. This new requirement will cause unnecessary delays in both the execution of lab tests and receipt of the results for SNF patients, which will result in delays in treatment—which is unacceptable to the SNF community.

Specifically, SNFs cannot and will not delay when patients need STAT lab tests, and if physician signatures cannot be received immediately. Patients will be transferred to local emergency departments via ambulance so that they can receive the tests in a timely fashion. Forcing facilities to send patients to the hospital for clinical laboratory tests is an action in direct contradiction to the stringent regulatory mandates regarding timely and high quality nursing facility care. It would also be a complete negation of the efforts of our provider members to provide the highest quality care possible. The SNF setting is unique as compared to other inpatient or ambulatory settings, with regard to physician practice patterns. Physicians are not present on a daily basis in the SNF, and are often consulted over the phone with the nurse recording telephonic orders into the medical record (the chart), not only for lab tests, but also for prescriptions, therapy services, and other care modalities- cosigned when the physician is next in the SNF within a 7 day period. This process must be adhered to in order facilitate timely care. AHCA is providing CMS with further critical detail on clinical laboratory services to nursing facility beneficiaries.

Special Concerns of Dialysis Facilities

Dialysis facilities treat patients who have a chronic condition, end stage renal disease; most of these patients eventually quality for Medicare. Physicians see the patients, evaluate them, and sign standing orders and protocols which provide for the care of the patients during their dialysis sessions; these signed standing orders and protocols include laboratory tests. These orders are kept in the patients' charts, usually an electronic chart in most facilities. Laboratory requisitions for standing order and protocol tests are usually generated electronically. Physicians see patients during the month, but are not usually present at each dialysis session for all patients; care is routinely given by nurses and NPs, with the help of patient care technicians.

When a patient has a problem not covered by the signed standing orders or protocols (fever, signs of infection, etc.), the nurse calls/notifies the physician, who might order additional lab tests, among other things. This typically is handled in one of two ways: (1) the nurse documents the telephone order in the patient's chart, which in today's world is usually electronic, and carries out the order, such as drawing a sample for a lab test and sending it out, usually to a local lab for a "STAT" test, using a paper request; (2) if the doctor is connected to the patient's

electronic chart, he will add an order to the chart via his own terminal, Blackberry, etc. Again, the nurse will carry out the order to the local lab using a paper requisition.

Why cannot a notation on the paper requisition to the local lab state "Documented order in patient's chart" and meet the requirements for "accountability"? Requiring a physician's signature at that point, in a non-routine situation, is contrary to the operations of the dialysis units and will cause undo hardship and delay. Staff will instead find a "work around" to give needed care to their patients; this will do nothing to address CMS' concerns about whether the physician ordered the tests – which is already documented in the electronic chart.

QUESTIONS AND COMMENTS RECEIVED FROM AMA MEMBERS ON THE NEW PHYSICIAN SIGNATURE ON LAB REQUISITIONS REQUIREMENT

Questions

- How will this new requirement increase quality of care?
  - How will CMS ensure that this new requirement does not impede access to care or increase the cost of care
- What is the rationale?
  - There is no widespread documented fraud involving lab requisitions, and signing a requisition will not stop intended fraud so why is this needed?
  - Why is this requirement needed if physicians already document the lab orders in the patient's medical record?
  - In order to effectively educate physicians about such a substantial change in their workflow, it is necessary to explain why they need to do this.
  - What problem does this change address?
  - How does it make things better?
- There are several questions involving this requirement and use of EMRs:
  - In situations when a physician uses an EMR but there is no lab interface will CMS still require the paper requisitions to be signed?
  - In situations when a physician uses an EMR to send the order to the lab but the order results in a fax being received will a signature still be required? If so, how should the signed order be sent? Matching up a signed paper requisition to an order received from an EMR via fax could create significant confusion for the lab.
  - Are lab orders submitted via EMR considered requisitions or orders? More clarity is needed over the difference between these two especially in the case of EMR use.
  - Will electronic signatures be permitted?
- How is a stamp any different from a document that was faxed that contains a real signature?
- Can lab reqs be signed in advance of the req being completely filled out?
- How should orders be handled when a patient needs lab work and the doctor is not present to sign the req?

COMMENT	TYPE OF CONCERN
I am writing to you about the requirement that all outpatient orders for X-rays and labs must have an original physician signature on them. This has put a hardship on my practice because the local hospital where we sent much of our labwork required that we manually sign all the requests for labwork (25-30 forms) daily. This is in addition to the many other forms we have to sign for our patients to receive diabetic testing supplies, home health orders, prescriptions, etc. In larger towns, hospitals can have the orders signed electronically, but we do not have	o Burdensome. o No evidence there are fraudulent lab requisitions being signed o Access to care

this technology. 'The lab and X-ray departments are afraid to run a test without the signature for fear that someone at CMS will come in and not pay for the test. Our county has run between 15-20% unemployment the last 2-3 years, and the our small hospital is on the brink of bankruptcy. It cannot afford to lose any revenue. As a taxpayer, I too am concerned about fraud and abuse, but I can't see where this really helps much. If someone is going to commit fraud, they won't hesitate to sign or forge a signature. For almost 20 years, I have practiced by giving orders which the staff has followed. Most of the paperwork could be handled by my nurse or other staff members. I know of no major problems with the system as it was. This seems to be a solution in search of a problem. I have to stop many times a day to sign some order so my patients to get care. For example, the radiology dept. requires a signed order if they see something abnormal on a mammogram before they will do the further X-rays required. A woman may have to go home and reschedule tests which could have been done on the spot previously, causing needless delay and worry. One final thought. Doctors are only human. We are subject to the same distractions others face in their work caused by stress and frustrations. Do you want me concentrating on what is causing your dizziness or chest pain, or what that spot on your chest X-ray is , or on making sure the paperwork is done correctly?	
I record in my office notes: 1. Every lab test I order (CBC, U/A, Lipids, etc.—and most of these are done in my office) 2. Every ancillary test such as CT scans, MRI's, Holter monitor, stress testing, etc 3. Every referral for consultations to other physicians I have specific locations within the chart to file results for each type of test/referral letter, and nothing is filed without a signature and a date indicating the action taken with the result. What my office record and paper records lack, however, is a valid system for following up to ensure that the referral occurred or that the ancillary testing was actually	o Lab orders are already documented in the medical record o Adds to workflow

performed and received. We rely on telling the patient "if you do NOT hear back from our office personally within ten days of performing this test then PLEASE contact us to make sure we received the result". I do personally keep a copy of such referrals at my nurse's desk and she checks off when we receive the test/referral result back in our office; this is crude but effective and relies upon our individual compulsiveness to keep us straight. We have such a solid relationship with our patients over such a long time that the follow-ups are really pretty easy.	
There is also a need for the results to be signed when they are read, and possibly a note to indicate any action taken. The EMR helps a lot with this. Every order that is placed has an expected and expiration date that pops up in an "Expiring Orders" folder if it is not done. Tracking referrals and tests is a requirement for passing the office assessment part of our malpractice company's review for premium discount, not to mention a good medical practice. Similarly, all results return into the EMR where they are reviewed and signed. A "Result Note" or letter/phone call to the patient can be done that is attached to the result.	o EMR handles the orders. o In this case it appears this practice would be exempt from new rules.
We have An EMR system in our office which I request a lab or test and it is sent to the lab with the appropriate codes electronically. Some paper requests are given to patients who come from rural referral hospitals of clinics. I do not recall physically signing a lab request for at least a year. Ours is transmitted to our regional lab electronically but other labs our done by paper requests	o Additional workflow.
I can't order a lab test unless I put it into the EMR. Everything has to be signed off, so signing a requisition is truly duplicative.	o EMR used, however, unclear whether lab req is received electronically (if so new requirements does not apply); if not requirement could apply.
Our orders go electronically in house and to the hospital and to the outside referral lab; wherever we direct them.	
Although my office system does not allow orders to be entered at this point, many systems that allow it will send an electronic fax to the lab which is then printed and entered into the lab system by the lab secretary manually. This is the way ePrescribing started and is still in effect for many of the larger and older, order entry systems whether you are talking about labs, xrays, images, prescriptions,	o EMR used but orders result in a fax therefore new requirement could apply. o As physician notes, many lab orders submitted electronically produce a fax.

referrals for consultations, etc. Progress is being made to get more sophisticated, but will are still not there in terms of 100% computer to computer messages. It's still mostly computer to fax, (if paper is not used in the office) except for the eRx network. There are also "fail safe" systems that will "drop the order to fax" if the computer message does not go through. Some systems actually send an electronic fax to the lab and also print out a duplicate copy locally. There are physicians who also do this with prescriptions, especially for controlled substances.	
This policy is not appropriate or reasonable.	o Burdensome.
Many tests are appropriately ordered on patients through phone contact or an order to a staff person through the EHR. To now go back to a paper order form is a logistics nightmare and will definitely add minutes if not hours to already burdened staff. Many patients may not be able to come into the office for a handwritten signature and will not be able to get routine laboratory tests at appropriate intervals. Maybe the people at CMS can step out of their office and understand our workflow and then reconsider this policy or maybe their can step forward and help us with staffing to implement an bureaucratic burden.	o Workflow interruption. o Patient access.
I strongly feel that this extra step Medicare is requiring from physicians to sign all lab req's would be burdensome and time-consuming. Additionally, what is the purpose and rationale behind this mandate? I'm obviously ordering the tests (my name is listed on the req)...so why require the sig as well? And we order our tests electronically, so I'd have to order it electronically (as the Medicare Meaningful Use Program requires), then have my phlebotomist track me down with the print out to sign it. Kind of ridiculous in my mind.	o Burdensome. o Rationale unclear. o Duplicative workflow with paper and EMR.
I find it onerous to sign multiple lab orders sheets. This regulation needs to be rescinded.	o Burdensome.
As a primary care physician I already limit my acceptance of Medicare patients due to poor reimbursement, and I do not "participate". Adding additional signing requirements will inhibit me even more. This will require the waste of an assistants time after completing the requisition, finding me and having me sign it. It may delay getting labs sent out for processing, which can hamper patient care. There	o Access to Medicare physicians. o Patient access. o No documented fraud. o Burdensome.

is no reason to suppose that labs are going to be sent out from a primary care office without the physician or other clinician ordering them. There's no incentive to do this, no fraud to be perpetrated, etc. In addition, the "order" as such can easily be viewed and verified in the medical record as it reflects the physician's plan for the work-up. I can allow my medical assistant to do virtually anything I can do, if I want to, removing sutures, performing injections, ear washes (which can permanently damage hearing if done improperly) etc., but according to this bureaucratic idiocy I can't allow the assistant to take my "order" from the chart or service slip and transfer it to a lab requisition!	
In a time in history when we are trying to be efficient, see more patients per day to keep our doors open what purpose would a physician signature on a lab order serve. The ordering physician is held responsible for ordering the correct lab even if their signature is not on it. Electronic medical records in place and a doc directing their nurse to order the prescribe that and create efficiencies of well trained staff in an office. This is just another thing to slow providers down. If you want to be electronic – you can't go backwards.	o Rationale unclear. o Ordering physicians already held responsible. o Burdensome.
CMS either wants medical records to be electronic or not. They have to stop adding unnecessary layers making the EMR and its use less efficient.	o Use of EMR makes this requirement duplicative.
I wanted to inform you of another example of how this signature rule adversely affects patient care which just happened to me last week. On Friday morning a patient called the office having problems. My nurse was able to get me in the operating room and I instructed her to have the patient get an xray and see me in the office that afternoon as an add on patient. This patient was well known to me and I was trying to deal with her problem in an efficient manner prior to the weekend and without going to the emergency room. Well guess what? The hospital would not do the xray without my signing the order! I was tied up outside of the office and could not sign the order. I don't think CMS has thought through their signature rule very well. I have yet to have anyone say what the purpose of the rule is and what it is to accomplish. All it does is put up road blocks to physicians trying to care for their patients and adds more paperwork for them. Please pass this additional example on the CMS	o Patient access.

folks.	
I suspect the rationale for this requirement was to minimize fraud and abuse by entities that might perform testing or imaging on Medicare patients without the specific authorization of a licensed physician, thus the signatory requirement. The unintended consequence, of course, is the delay and sometimes lack of appropriate, timely care for Medicare patients. In addition to your good example, let me offer mine: 1. When patients are discharged from the hospital, I write in the discharge orders follow-up testing such as CT scans, PET scans, X-rays, lab testing, etc. 2. This is done as a part of necessary, appropriate care, and usually is to be done a couple of days or weeks after discharge from the hospital. 3. To NOT do the above in many instances represents inappropriate and sometimes BAD care; even malpractice. These patients need these results to ensure that their disease process is improved and so on. 4. The problem is that simply ordering the test in the discharge paperwork and "signing" the order IS NOT GOOD ENOUGH for the regulators. The lab and radiology departments then will not perform the requesting testing unless I AGAIN sign a separate sheet of paper days or weeks later repeating the order – thus delaying or refusing to perform needed medical studies for Medicare patients. Obviously this is not the intent of the Medicare signature requirement, and we must improve the current system.	o Order already documented in the medical record. o Burdensome and duplicative.
I am having many complaints from physicians about this especially primary care doctors in the rural areas. Hospitals are refusing to do the lab work now without their signature. A verbal order or nurse's signature is no longer good. They have many patients in nursing homes and many patients they handle over the phone and it is not easy to sign all of these orders. Some are for routine INR studies for their patients on Coumadin and they should not have to sign all of these orders. Quite often I will tell my nurse to get lab work on a patient, and for me to have to find an order sheet and physically get that piece of paper to the lab for the test to be done is ridiculous. No wonder	o Rural patient access. o Rational unclear.

physicians are getting frustrated and tired of the system. We are trying to take care of all of our patients and the government is putting up roadblocks. I would like an answer to the question, "What good does this rule do and how does it improve patient care?" Also, "Why was the rule ever made in the first place?" It does not prevent fraud! If I were going to commit fraud then I would be happy to sign all of the papers. It is not fair that it only applies to paper orders and not computerized orders. It will motivate physicians to pre-sign a stack of orders to get around this rule. That way their nurses will be able to fill the order sheets in and get the needed tests but what does that accomplish? Nothing. It even makes fraud more likely with the pre-signed order sheets left lying around. This is typical of the government as far as establishing rules that don't make sense and actually incentivizes the person who is suppose to follow the rule to try and get around the rule. "Obamacare" is full of these type things that have perverse incentives.	
I am the medical director of a nursing home. Every month, I sign a new set of 30 day orders on my patients. Included on those orders are things like "PT/INR every Tuesday to monitor Coumadin treatment", or "Hgb A1c, lipid panel, and CMP every 6 months to monitor diabetes" [required by CMS for P4R]. Now the hospital will not accept those orders unless I ALSO sign the lab requisition form. Further, if a patient has an abrupt change of status, especially in the morning, I used to be able to verbally order lab work & imaging over the phone to have ready for my review when I see the patient that afternoon. This requirement delays by at least 24 hours the data I need to make a diagnosis or treatment decision. The other option to delayed diagnosis is to have the patient travel to the hospital in an ambulance [transport cost] for urgent care [which is paid at a higher rate than physician LTCF visit], further crowding our local emergency department [which over-tests and further increases charges for this episode of illness]. The transportation also disrupts the patient's care & rehabilitation, frequently stressing him/her by taking him/her out of a familiar environment into one they have little control over.	o Patient access. o Increased costs to the system.

Overall this appears to be a solution in search of a problem and will cause an increase in health care costs to CMS and decrease quality & efficiency in care delivery to prevent a few people from committing fraud.	
CMS is incentivising EHR. Physicians have spent a significant amount of money to have interfaces written with reference labs so that orders and results are bidirectional. With CMS rule, the order will need to be printed from the EHR, sent to the physician for signature, sent back to phlebotomy to connect with barcoded specimen to be sent to reference lab. All lab orders initiated in the EHR have Drs electronic (digital) signature on file. This is cumbersome and uses more paper.	o Under this scenario presume physician would not have to print the order?
Aside from whether a signature is needed, what is an acceptable signature? We recently had "hand stamped signatures" on faxed lab orders rejected by our labs. Curiously, they agreed to accept "real faxed signatures." Given that fax machines digitize signatures there is no way a fax machine can ever deliver a more verifiable signature than is possible with a hand stamped signature. Both are rough digital approximations of the original signature. Still the myth of "real signatures" on faxes seems somehow better to staff members unwittingly repeating policies that were poorly thought out. The existing system of faxed signatures (if required) works well enough until a more secure electronic signature technology becomes widespread. Even CMS does not foresee this happening until at least 2016. Until quandaries like this are resolved the entire question of required signatures has many implementation issues and should be put off until better technology is available.	o Clarity around signature is needed.
My office staff will frequently generate a lab requisition on my order but when I am not present. Timing of labs, particularly for infertility patients, is critical. At times, the requirement for a physician signature on every request would delay work-up, costing the patient at least a full cycle. Rubber-stamping all lab requisition forms in advance could potentially solve this problem but what's the	o Patient access. o Increased costs. o Workflow interruption.

point. I would propose a compromise in which a signed physician's order must exist for each lab test ordered. That will require chart documentation of the request without the requirement for signature on the requisition form. The current provision will stick patients in the middle - they will show up to the lab without a signature, having taken time to get the labwork performed - the lab will refuse and the patient will need to return to the MD office. Alternately, the lab will have to fax a form to the MD office urgently for signature. If the doc is not there - too bad!! Some physicians have standing orders for patients who have certain conditions. For example, the physician signs an order that states that all women with abnormal mammograms will have diagnostic views and ultrasound as indicated. For labs, we could propose a signed order for all patients who have lab requisitions - or there could be electronic signatures or signature stamps permitted.	
I am unclear how this requirement would be required on electronic interfaced ordered diagnostic laboratory tests in a secure system that requires a login and password. Also, documentation of the tests ordered should be available in the patient's chart which is authorized and signed by the treating provider. Having a separate signature on the requisition seems to be redundant and inefficient.	o Clarification on this requirement and EMR use needed. o Lab order already documented in patient record. o Requirement is duplicative.
What if a patient returns for a lab test in the fasting state at a date or time that a physician is not in the office? Can the requisition be signed earlier or later than the actual service delivered? If so, how is this any different than requiring a physician to sign off on a lab result when it is complete (which is good practice anyway)? Beyond that, why is this an issue? Has there been an identified concern that a nurse or other ancillary personnel completing a lab requisition somehow increases the chance of fraud?	o Clarification on when lab req can be signed needed. o No documented fraud.