MEDICARE BILLING TROUBLESHOOTER FOR CLINICAL TRIALS pdf

1: Reducing Clinical Fraud

â€¢ Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria.

The breakneck speed of medical advances and the increased effort to base clinical decisions on reliable evidence place clinical trials in an ever more prominent position between medical innovation and medical practice. Expanding the evidence base for health care interventions is clearly in the interest of both taxpayers who support Medicare and beneficiaries who receive services. The impression is widespread that some patient care in clinical trials is not reimbursable under Medicare. But except in the case of certain investigational medical devices and a few instances of "coverage with conditions," the Health Care Financing Administration HCFA has never explicitly laid out exactly what should and should not be reimbursed. A large proportion of patient care provided in clinical trials is routineâ€”care that would be eligible for reimbursement if delivered outside of a trial. But not all such costs for clinical trial patients are paid. Increasingly over the past five years, uncertainty about reimbursement for routine patient care has been suspected as contributing to problems enrolling people in clinical trials. Clinical trial investigators cannot guarantee that Medicare will pay for the care required, and they must disclose this uncertainty to potential participants during the informed consent process. Extending Medicare Reimbursement in Clinical Trials. The National Academies Press. Thus, patients considering whether to enter trials must assume that they may have to pay bills that Medicare rejects simply because they have enrolled in the trial. This report recommends an explicit policy for reimbursement of routine patient care costs in clinical trials. It further recommends that HCFA provide additional support for selected clinical trials, and that the government support the establishment of a national clinical trials registry. These policies 1 should assure that beneficiaries would not be denied coverage merely because they have volunteered to participate in a clinical trial; and 2 would not impose excessive administrative burdens on HCFA, its fiscal intermediaries and carriers, or investigators, providers, or participants in clinical trials. Explicit rules would have the added benefit of increasing the uniformity of reimbursement decisions made by Medicare fiscal intermediaries and carriers in different parts of the country. Greater uniformity would, in turn, decrease the uncertainty about reimbursement when providers and patients embark on a clinical trial. Five specific items were to be studied: Three committees were established to carry out the tasks, including this one to focus exclusively on the clinical trial question. The clinical trial committee is aware that the question of reimbursement for care in clinical trials is not a new issue. Clinical trial investigators, patients, and potential volunteers have increasingly seen as a problem the lack of coverage for routine patient care that would be covered if the patient were not in the trial. Cancer activists and organizations, including cancer centers, were the most active agents in bringing this issue into public view. Several draft bills have mandated that Medicare cover routine care costs in clinical trials. Clinical trials are intended to discover or verify the safety and effectiveness in human beings of interventions to promote well-being, or to prevent, diagnose, or treat illness. Other definitions are more expansive, including even the first use of a new intervention without a formal plan or any type of comparison. Our definition is limited to the activities that could be eligible for having at least some patient care costs reimbursed under Medicare. This definition does not include a new intervention applied by a single practitioner to a single patient in what might be the earliest phase of innovation. It applies only after a protocol describing the intervention, the types of patients, the endpoints, and other details has been developed to find out whether an intervention is safe and effective for a given condition. For all types of interventions, the definition encompasses the comparative trials that are needed to produce definitive evidence, and for drugs and devices, in particular, the definition also includes early trials that may be focused mainly on safety and have only one intervention group "single-arm trials," i. The central importance of research to medical practice is relatively new. What is often cited as the first deliberately randomized clinical trial took place in the late s to determine the efficacy of treating tuberculosis with a newly invented antibiotic, streptomycin. Over the years, occasional tragic complications associated with new drugs or devices led Congress to authorize regulatory agencies to mandate clinical trials to determine safety and efficacy before

drugs and devices could be marketed in the United States. Although at least a minimal level of evidence from clinical trials is required for the legal marketing of drugs, biologics, and medical devices, information on whether a new drug or device works better than an old one is not required by law. And there is no such legal requirement to demonstrate safety or efficacy, to say nothing of superiority over existing procedures, for a new procedure that does not involve new commercial products. As a consequence, although many decisions are being made on the basis of sound evidence from clinical trials, the use of many medical interventions, old and new, does not rest on solid evidence. The new emphasis on evidence reflects the realization that intelligent decisions require substantial information that properly conducted clinical trials can provide. Notwithstanding any other provisions of this title, no payment may be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member. Since the inception of the Medicare program in the mids, the phrase "reasonable and necessary" has guided Medicare reimbursement. Although little explicit policy has been issued on the topic, this clause has been the basis for excluding reimbursement for at least some routine patient care in clinical trials. This Medicare interpretation has historical roots in the private insurance sector, whose policies in the s and still, in , exclude coverage of services in clinical trials GAO, In addition, private insurers have been involved in supporting specific trials e. Despite the lack of an explicit Medicare policy excluding reimbursement for routine care in clinical trials, HCFA has signaled its intent in several ways in recent years. In , HCFA asked the Office of the Inspector General OIG of the Department of Health and Human Services DHHS to investigate whether hospitals were billing Medicare "improperly for millions of dollars worth of surgical procedures involving unapproved medical devices," specifically investigational pacemakers, defibrillators, and other cardiac devices in clinical trials. In a hearing of the Subcommittee on Investigations of the Senate Committee on Governmental Affairs, an official of the OIG reported their finding that most of the hospitals they investigated had, in fact, improperly billed Medicare for implanting investigational devices. What might not be clear from the OIG account is that it was not only payment for the investigational devices themselves, but for the implantation procedures, as illustrated by comments of others, including at least one HCFA official. Most Medical Directors interviewed by GAO also stated that they make exceptions and do cover clinical trial costs on a case-by-case basis. These instructions stated clearly that "medical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary. Additional instructions in these manuals dealing more generally with Page 6 Share Cite Suggested Citation: The clearest indication that routine patient care is not reimbursable in other types of trials is found in a report by the General Accounting Office GAO, on reimbursement by HCFA for Medicare beneficiaries in cancer clinical trials. HCFA has not issued any new language to change clinical trial reimbursement policy since the change for trials involving Category B medical devices, and no HCFA statements contradictory to what is presented here were found in the course of this study. The agreement between HCFA and FDA constitutes the only formal statement of policy about reimbursement of routine patient care costs in clinical trials, authorizing reimbursement for those costs in most trials of investigational medical devices. What information is available suggests that a sizable proportion is paid for by insurers, including HCFA. This conclusion derives from: The official also made clear in his testimony that Medicare would have paid for patients in the trials to have the standard device implanted. Page 7 Share Cite Suggested Citation: Providers violated no clear rules in billing for routine patient care costs in clinical trials because no such rules were ever codified. But the gap between the impressionsâ€”and statements of responsible HCFA officialsâ€”regarding reimbursement rules on the one hand, and reimbursement practices on the other hand, should be ended. Medicare should reimburse routine care for patients in clinical trials in the same way it reimburses routine care for patients not in clinical trials. This principle applies to payments for physicians and other providers, roufine laboratory and other diagnostic tests, and any other services that comprise routine care for a given patient. All coverage and medical necessity rules and all other restrictions that apply to patients not in clinical trials would apply to care in clinical trials. The committee recommends a broad definition of clinical trialsâ€”including all phases and legitimate designs and all sources of sponsorship government, industry, or other â€”all of which should be equally eligible for reimbursement. This definition does not mean, however,

that any treatment simply called a "clinical trial" would qualify for reimbursement. To qualify, a clinical trial must have a written protocol that describes a scientifically sound study and have been approved by all relevant IRBs before participants are enrolled. HCFA should articulate criteria for an acceptable trial and IRB review, which investigators would apply to determine whether their studies are eligible for reimbursement. Medicare should reimburse routine patient care costs, but not all costs in clinical trials. These costs should remain the responsibility of research sponsors, private and public. Medicare should continue its current practice of reimbursing costs of treating conditions that result as unintended consequences complications of clinical trials. HCFA should reimburse surgeons or other practitioners for treating patients in randomized clinical trials involving procedures that are variations or modifications of accepted procedures, or new uses for accepted procedures. Under the current interpretation of Medicare reimbursement rules, the committee believes that surgeons and others performing surgical or other procedures in trials might not be eligible to be reimbursed for those services. Therefore, the committee recommends that procedures that have become widely accepted as a part of standard medical practice, but which, as part of a clinical trial, are being rigorously evaluated, or are being modified or applied for new indications to determine the incremental risks and benefits, should be eligible for reimbursement at the rate for the standard procedure. Conversely, types of procedures for which initial questions of safety and efficacy have not been resolved would not be eligible for reimbursement. Unlike the basic recommendation regarding routine patient care costs, which applies to all clinical trials, this recommendation would limit reimbursement to randomized trials the equivalent of "phase 3" trials for drugs and devices. The committee believes this limitation is appropriate in order to avoid providing reimbursement for uncontrolled experimentation by practitioners. The introduction of new drugs and devices is governed by FDA under a formal system that involves phased trials. In contrast, the introduction of new procedures is not governed by any regulatory authority. In their early phases, procedures are modified or tried for different indications in clinical practice, but rarely in formal trials. However, once a new or modified procedure has been defined and developed to the point that it is distinct enough from the predicate procedure, it may be tested against the standard treatment the predicate procedure or other accepted treatment in a formal randomized trial. Medicare should provide reimbursement to the surgeon or other practitioner for treating patients in such trials. The committee is expressing no judgments about when trials of procedures should or should not be carried out, or who should be involved in them if they are. It applies only when a trial of a procedure is being doneâ€”for all the reasons that trials are doneâ€”and claims for reimbursement for the procedure are submitted by practitioners. These definitions describing what is and is not allowed will be applied in the field when claims are submitted. HCFA should not be required to rule routinely on the eligibility of procedures before bills may be submitted. In the same way that providers are responsible for following reimbursement rules for all services under Medicare, they will be responsible for applying the rules appropriately in the case of procedures in clinical trials. Fiscal intermediaries and carriers audit these interpretations by providers in clinical trials, as they now audit bills from providers who are not in clinical trials. Advice or an interpretation could, of course, be requested of HCFA at any time. In addition, HCFA would retain the right to initiate its own review, without being asked, if it believes there is an issue to be explored, to carry out a random check, or for another reason. The committee recognizes that creating definitions that neatly separate "category A" and "category B" procedures will not be simple, and disagreements are inescapable about where the line between "A" and "B" should be drawn in specific cases. Wherever the separation lies, some procedures will fall into a "gray zone. To deal with cases in which uncertainty remains, HCFA should set up a process to role quickly on reimbursement eligibility. With accumulated experience, the number of gray zone cases should decline, as has been the case with FDA classification of devices into categories A and B. The committee has not attempted to specify an institutional mechanism under which HCFA might carry out the tasks required by this recommendation. For claims submitted in accordance with both the fundamental recommendation No. The member committee will function through specialty panels of not more than 15 members each. Page 10 Share Cite Suggested Citation: Claims should be submitted in the same way they are for treatment outside of trials. Practitioners and institutions would be expected to submit reimbursement claims for services to patients in clinical trials under rules

outlined in Recommendations 1 and 2. With a clear statement of reimbursement policy, such claims should pose difficulties no different from those arising in the administration of coverage and reimbursement rules for claims for care outside of trials. Investigators and providers would not be routinely required to submit documentation about the trial to HCFA, but HCFA could, at any time, request such documentation to confirm that the clinical trial meets current standards for scientific merit and has the relevant IRB approval. If Medicare or trial sponsors fail to cover clinical care costs, patients should not be billed for those costs above what they would pay if they were not in a trial. This recommendation is not one that can be enforced as part of a reimbursement policy by HCFA; however, the committee believes it is an important principle that could be adopted by clinical trial sponsors and investigators.

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2: Medicare and the NCD | Applied Clinical Trials

Medicare Clinical Trial Policies The current Clinical Trial Policy can be found by clicking the link below (under Related Links inside CMS) labeled " Current Policy - July NCD ". Clinical trials are key to understanding the appropriate use of medical interventions of all types and informing payers about what services to cover.

Busby There are many different ways that fraud can occur throughout a single clinical trial. There are also many examples provided to show that fraud is an issue when it comes to clinical trials today. It is not hard to reduce this fraud as it only takes one person to notice that it is occurring and a stop to the trial can come immediately after. The FDA has made numerous suggestions so that an individual can prevent fraud, including the following: Identify source data and verify its existence and accuracy against what was reported. Missing records are a key indicator of potential fraud. Fabricated data will generally point in the direction of inconclusive results or results favouring the test article. Observe if all documents are prepared or written by the same person. Notice the repeated pattern of data from a study. Identify departures from anticipated trends. Be alert to whether the firm has the expertise, capability and equipment to perform the procedure or test associated with the data. Determine the sequence of events and amount of work related to generating the data and consider whether it was physically possible for the individuals performing the procedure to have done so in the time frame and sequence indicated by the records Horowitz, The steps above should be followed by all people involved in the clinical trial process and the result would most likely be that fraudulent data would not likely pass through the trial. Some may think that all people are not capable of going over data correctly to notice various data falsification or fabrication and this is where a statistician should come into the trial. According to Buyse, et al. These are all signs of a possible fraud in data, so it would make you think, why are statisticians not involved in every clinical trial conducted? On top of the suggestions that are supplied by other authors, I have found some simple suggestions as a result of some of the examples of fraud provided above. Just like with many other deadlines in life, people tend to procrastinate and even may result in falsified data supplied to the IRB. At minimum I believe that investigators should be required to report to their IRB more frequently than once a year. This system would not allow an investigator to falsify reports, as the data would need to be provided to the IRB that instant. Again, we have seen above that investigators are currently not required to disclose payments or other incentives related to recruitment to their IRB. Money is a major issue in this field as it is a business and everybody needs to make a profit in the end to survive. We have seen how much trouble recruitment incentives can be in a clinical trial, so the amount of money a person is making, especially in regards to recruitment is an important matter when it comes to finding who is the appropriate investigator for the job. The IRB would than be able to judge on if there is any conflict of interest or not and find the appropriate investigators for the job. I realize that there can be many other solutions for this problem, but these are only a few that would at least move the process in the correct direction. This is a field that any form of fraud is unacceptable and until we reach the day that there is no fraud occurring, we still need to make the appropriate changes. People depend on these products on a daily basis and we need to make sure that each consumer is getting the appropriate product and not something that has been past through the process as a result of fraud. The role of biostatistics in the prevention, detection and treatment of fraud in clinical trials. Statistics in Medicine, 18, Fraud and investigator integrity in clinical research. Clinical Research and Regulatory Affairs, 12 2 , This information has been published by the International Biopharmaceutical Association www. Please note this information does not give any medical advice.

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3: Commitment to Privacy - Virginia Commonwealth University

Medicare will help pay for some of your costs if you join a covered clinical research study. Medicare pays routine costs for items and services, including: Room and board for a hospital stay that Medicare would pay for even if you weren't in a covered research study.

By Applied Clinical Trials Editors Applied Clinical Trials Volume 22, Issue 2 While there is no single correct way to develop process compliance controls to meet federal clinical trials billing regulations around Medicare, standardization of the entire billing process is key. Establishing standards around a comprehensive clinical trial billing compliance program will help mitigate billing non-compliance risks. There have been numerous federal investigations and settlements involving improper clinical trials billing. Perhaps one of the most notable investigations involved Rush University Medical Center. In , Rush reviewed its clinical research operations and uncovered a number of errors in which Medicare was improperly billed for research services as routine costs. Effective July 9, , Clinical Trial Policy National Coverage Determination NCD from CMS, says Medicare covers the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. Previously, Medicare did not cover patient care costs associated with enrollment in a clinical trial. What are routine costs? Standard Medicare billing rules apply to items deemed routine costs under the NCD. If Medicare covers the costs of items and services outside of the clinical trial, then they are covered during the clinical trial. A clinical trial must meet the following requirements under the NCD to receive Medicare coverage for routine costs: The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage. The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have a therapeutic intent. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group. Exhibiting these three criteria, however, does not automatically qualify a clinical trial for Medicare coverage of routine costs. There are seven desirable characteristics that clinical trials must possess. Some clinical trials are automatically qualified as they are presumed to meet the following characteristics: The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use. The trial does not unjustifiably duplicate existing studies. The trial design is appropriate to answer the research question. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully. The trial is in compliance with federal regulations relating to the protection of human subjects. All aspects of the trial are conducted according to the appropriate standards of scientific integrity. These items and services are not covered by Medicare. The financial disclosure language in the informed consent form also must be examined carefully. Items and services disclosed to the research participant as being free or paid for by the sponsor or third-party payer are not billable to Medicare. Clinical trials billing compliance seems like a simple concept: Many stakeholders question whether the Medicare rules accomplish their goals, and in fact, the CMS has proposed a number of changes in an attempt to clarify gray areas surrounding the rules. A comprehensive clinical trial billing compliance program can help organizations establish standards to meet regulatory requirements and provide sustainable organizational consistency.

4: Qualifying Trials > Medical Research Billing Compliance | YCCI | Yale School of Medicine

Billing/Coding of Routine Costs. Medicare covers routine costs of qualifying clinical trials. Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries and services that are provided in either the experimental or the control arms of a clinical trial.

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