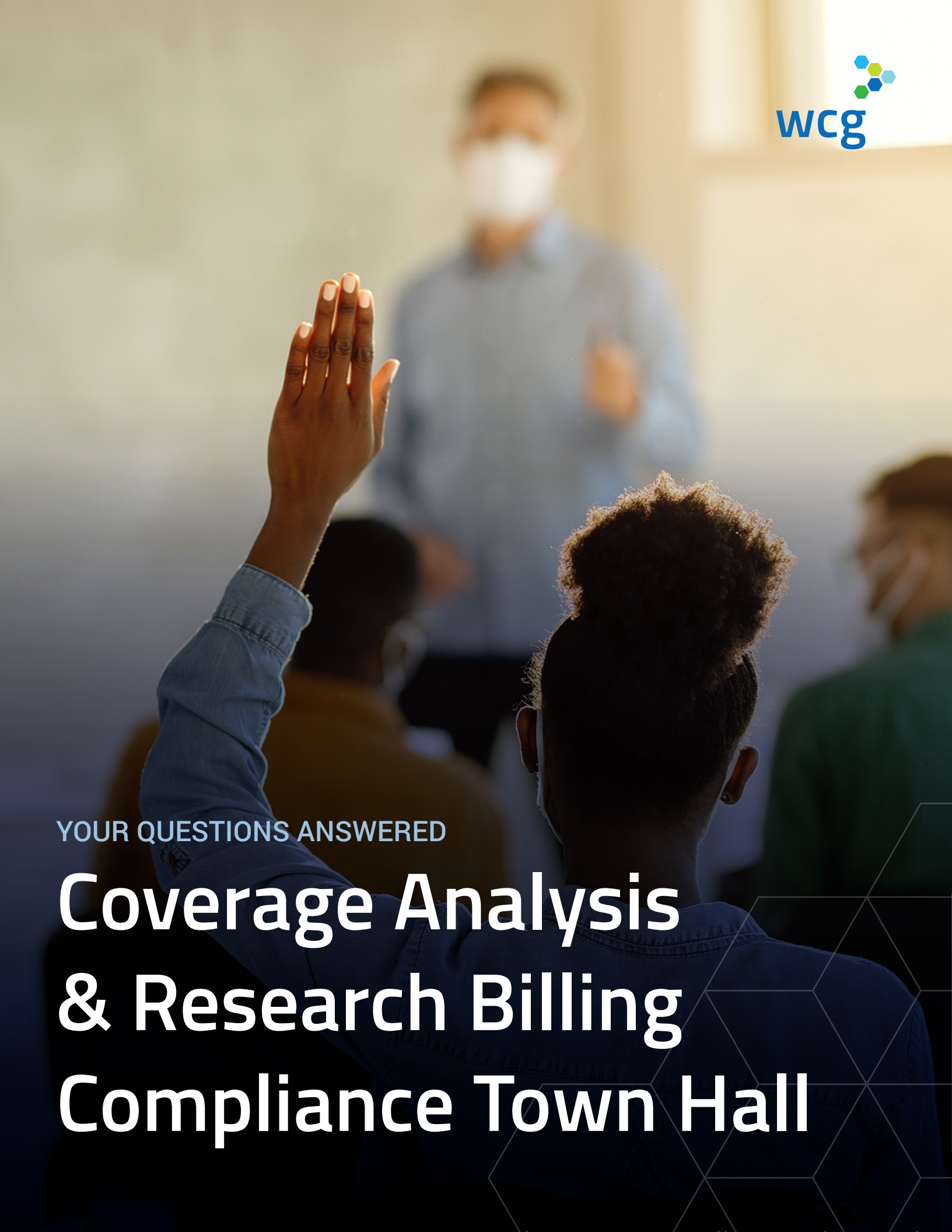

YOUR QUESTIONS ANSWERED

Coverage Analysis & Research Billing Compliance Town Hall

We recently hosted a round table event with leaders of institutions and research sites to identify critical challenges sites face today. To follow up, our three-part webinar series discussed solutions to these challenges for research sites, institutions and health systems. The second webinar was a live Coverage Analysis and Research Billing Compliance Town Hall to address specific program questions. This article provides a recap.

Q: When should you do a coverage analysis?

A: Coverage analysis should be one of the first activities in the study start-up process once you are selected as a site and have study documents from the sponsors – namely, the protocol, ICF and budget. Early coverage analysis will tie directly into the budget and contracting process. Often, it uncovers special protocol requirements that may impact discussions about logistics, e.g., extended observation periods after dosing or a special lab processing requirement. Catching those issues in the coverage analysis process speeds start-up.

Q: How do you use a coverage analysis?

A: A coverage analysis adds value at several times:

Early on, it determines services required by the study protocol and identifies services not billable to third-party payers, which should then be negotiated into the sponsor budget.

Use coverage analysis after contracting (prior to first patient being consented) to ensure that your informed consent document, coverage analysis and study budget align with billable services. Also, consider any out-of-pocket patient expenses or charges that will go to insurance, ensuring that all three documents are synced.

The final utilization comes during the backend research bill scrub process, where clinical charges are reviewed and bucketed into “billed to study funds,” “billed to third-party

payer" or anything that is handled with "special circumstances," such as invoicing to sponsor.

Q: Is there a universal template available to create a grid?

A: There is not a universal version; most sites develop their templates based on preferences and needs. You might use one of the templates available online from various research sites or use a CTMS system.

If you are developing a coverage analysis grid, include a qualifying trial analysis section that shows whether the trial is qualifying. Also, include the different policies under which you can qualify a trial – such as NCD 310.1 or the IDE policy.

All templates should have a billing grid to input the schedule of events and add billing determinations. Set standard billing determinations, e.g., many sites use [R] for research that will not be charged to the patient and [S] for standard of care for Medicare to indicate who is paying for that item. Consistency is vital to avoid confusion.

Q: What's the best way to get started with a coverage analysis?

A: The best way to get started is to determine if it is a qualifying clinical trial under NCD 310.1 or the Medicare Benefit Policy Manual for devices. Then, build out the schedule of events. Read through the protocol ICF and sponsor budget to check for any items required by the protocol that might not be listed in the schedule of events. Next, mark anything offered as "paid by the sponsor" in the sponsor budget or "promised free" in the informed consent.

Q: Where's the best place to start when looking up coverage determination information - NCDs or LCDs? Or should you start with guidelines for that disease type?

A: After marking everything that the sponsor is offering to pay, open the clinical guidelines for the underlying condition to decide conventional care for that patient population. Also, look for any side effects of the investigational item to see if other labs might be billable using support from NCD 310.1.

Look for any other NCDs or LCDs that might apply to certain

items, and make sure to document the reason that the NCD supports or limits billing the item to insurance. Use that information to decide if an item can be billed, and make sure to document the support in the comments section of the CA.

Q: Why aren't there better or more user-friendly resources for looking up NCDs and LCDs?

A: The Medicare coverage database is the main resource for NCDs and LCDs, but it is not user-friendly. Coding software systems can link you to the NCD or LCD if you know the CPT codes; that is a more user-friendly approach. Then, we recommend bookmarking. Make a bookmark folder and bookmark the common ones that you see in protocols. Create a document to plug in your standard analysis if that NCD or LCD tends to apply consistently across protocols.

Q: What do you do when a sponsor has sites in multiple jurisdictions, and the LCDs limit coverage differently? How can we educate sponsors on the different determinations and then budgeting?

A: Most sponsors have sites in different jurisdictions, based on how many sites are participating in the trial in different regions of the country. Sponsors cannot address every possible LCD for a trial; the site must review the items and ensure that there is no NCD or an LCD that applies.

The sponsor should expect differences between sites across different regions. Within a region, different sites might interpret policies differently. Note that to the sponsor, if it is a bigger-ticket item you're not going to bill because of an LCD, you might be the first site in that region to ask them to pay for that; point out to them that you can't bill based on an LCD.

Q: Why do some sites choose to make all screening procedures paid for by the sponsor instead of insurance?

A: First, screening procedures done only to determine qualifications or eligibility for enrollment should be paid by the study; the coverage analysis will identify those. However, it can be challenging to some sites for several reasons:

- The timing of routine care services – Are you choosing to split your service?
- Elements of the screening visit billed to the sponsor vs.

third-party payers, as timing can be challenging – especially involving a PI or an investigator team with specialists or referrals from a primary care physician or other specialist, and if some services identified within the screening visit were recently performed by the previous physician group.

- Services provided prior to signing the informed consent – leading to issues in terms of whether the data can be utilized and shared or if it remains within the window.

Second, during the consenting process, there are advantages in explaining to potential participants that any services provided during the screening visit will be covered by the sponsor – not billed to a third-party payer.

Q: What if we cannot find a concrete, third-party justification for a comments field?

A: The comments field refers to your justification why the item is or is not billable to Medicare.

When there is no justification based on the Medicare research policies, many sites will ask the sponsor to pay for that item. If the sponsor does not agree, or if the PI pushes back, the site compliance department must decide.

Some sites have clinical SOPs; when a patient is admitted with this condition, they automatically order these tests for the patient, and those SOPs can also be used. Make sure there is no limiting NCD, LCD or other Medicare policy.

Q: How do private payers use Medicare guidance for coverage?

A: Private payers administer Medicare Advantage Plans; subscribers have the same benefits as traditional Medicare. Medicare Advantage Plans will follow Medicare more closely in terms of coverage decisions since, other than the administration fees, the dollars are coming from Medicare. Commercially available plans for populations younger than Medicare eligibility have no requirement that commercial payers or private payers will make the same determinations as Medicare does.

That issue becomes a challenge for sites as they navigate the coverage analysis and identify potential patient populations; they need to see the history and experience of their clinical sites with certain areas of coverage for payers (e.g., cardiac cath lab, EP lab, surgery). Ensuring that you are utilizing pre-authorization processes required by payers is more important than trying to identify whether Aetna or Humana will cover a service the same way Medicare does.

Q: What coding is required for hospitalized patients enrolled in a qualifying clinical trial with routine care services?

A: Sites that participated in COVID trials, especially inpatient COVID treatment studies, encountered this issue. The entire admission period was submitted as a single bill to the third-party payer. Coding for that episode of care was the same whether the participant was on the study one day or for 99% of their stay.

Inpatient billing biomedical rules do not require Q0 or Q1 modifiers in line-by-line service, making coding easier. Those expectations are there for inpatient care, regardless of whether the entire hospitalization was directly related to study participation with routine services included or whether only a portion was related to the study. The same coding is submitted to Medicare.

Q: Should devices be identified separately from the procedure as a line item?

A: Best practice in coverage analysis is to identify the investigational device on its line with its specific billing designation and modifier. Typically, the investigational device will have the Q0 modifier and a cost associated with it, depending on designation as Category A, provided free by the sponsor, or Category B, billable by cost. Identify that on a coverage analysis because within the episode of care, you will have that investigational device identified as a separate line, as well. It makes sense to call it out within coverage analysis specifically.

When working with your supply chain to ensure that a specific charge code is created for the investigational device, we recommend including that in the coverage analysis. With investigational device studies, there is often the device plus guide wires and transducers to be included in that bill.

Q: How do other sites keep track of amendments for the coverage analysis team? We seem to be the last to know, and it becomes a fire drill to update the MCA and the budget. This is largely an internal communication issue, but I'm curious if other sites have suggestions. Also, how often should you amend the coverage analysis?

A: We recommend reviewing and updating the coverage analysis every time there is an amendment, even if the only update is the protocol version date. If you wait until the amendment might impact the grid or the coverage analysis itself, there may be several amendments. It can be hard to track down precisely what changed if you are going from version one to version six.

As far as keeping track, communication is critical to ensure that the CA and budget team know every protocol amendment. We have several sites that require a team member to be involved in any communication from the sponsor to be aware of amendments.

Q: Do coverage with evidence development (CED) trials also need specific CMS approval?

A: Yes, these trials fall under two different policies. We typically see the CMS approval posted on the CED page for these trials. If you are opening one of these studies and your coverage analyst does not see it on the CED page or the IDE page. Contact the sponsor and ask if they plan to submit for that program.

Q: How does the Medicare secondary payer rule affect subject injury language in the clinical trial agreement, where the sponsor is asked to pay for study-related injury? Is letting Medicare cover for all complications a better approach?

A: The Medicare secondary payer rule originated due to workers' compensation claims or claims against general liability insurance for Medicare beneficiaries where someone else would pay the cost of the treatment. Medicare makes upfront payments to ensure that care is delivered in the hospital, or a caregiver can be made whole regarding the payments. Ultimately, it recoups expenses paid against the insurance policy. When a sponsor puts language into its

clinical trial agreement or an informed consent stating that the sponsor will cover the costs for treating a research-related injury or conditional services denied by insurance, they make themselves a guarantor. Medicare says, "If you are a guarantor, then you are primary and will be paying before we will."

This situation leads to confusion in research-related injury-type scenarios. There is rarely a true guarantee that all participants in a study will either be 100% Medicare beneficiaries or 100% not Medicare beneficiaries, so you will have populations with commercial payers providing their insurance. If the Sponsor assumes all patients are Medicare, and allows research injury to be billed to insurance you have the commercially insured participants that at a minimum have out of pocket expenses (co-pays, deductibles, and/or co-insurance) and perhaps complete denials for coverage. In these cases, a patient and the site can be caught between whether to bill the individual for services denied by insurance or find a way to help the patient through their helping hands or medical assistance program, which is cumbersome.

If the Sponsor offers to cover research injury costs, then Medicare secondary payer rule puts the sponsor on the hook for all Medicare beneficiaries covering those costs as well, which was not what the sponsor intended. The default language often says that if the sponsor is willing to pay those costs, we should ask them to cover all research-related injury regardless of payer. This is better for the study participant, as they do not have deductibles, coinsurance or copays running through their insurance. From the sponsor's perspective, it is better to bill it to insurance.

Q: How do you approach treating patients the same, whether they're in a trial or not, when it comes to billing insurance?

A: Patients on a study are treated by the investigators according to the protocol and based on signs, symptoms or clinical conditions where the physician investigator is using medical knowledge.

The protocol will govern the care pathway required by the investigator or the site, but the investigator can use their medical knowledge and do what is best for the patient.

The charges for services should be created in the same fashion whether the patient encounter was for research or routine care. Whether a physician uses a tick sheet for the physical exam or an electronic package, that process should be consistent. That entire process ensures that patients are treated equitably.

Q: How do other sites handle research tests or procedures that can be performed at several alternative sites to help with the current burden, such as a high volume of inpatients?

A: This situation became challenging for sites due to the pandemic, as certain areas of care were shuttered or overwhelmed, so studies were restricted or mothballed. The ability to create overflow pathways for alternative clinical locations to conduct visits, scans or labs is a regulatory issue, ensuring that those areas are correctly identified in the IRB approval packet. That may require amendments to add sites. If you are adding imaging centers or physical locations, make sure to update your regulatory package and have IRB approval for those changes.

Communicate with those new stakeholders for billing. Make sure they understand how research billing flows, how charges are created and that somebody will review those charges. Share study information with clinical sites, so they understand how they are being brought into that study.

Q: What can we do to make sure that the PI complies with billing rules?

A: First, have institutional policies requiring compliance of physician investigators with all research processes and policies. These policies and expectations should be embedded within your clinical privileging documents and processes; any physician or any caregiver wanting clinical privileges at your facilities will complete these every few years. A section allows them to identify their intention

to participate in research, helping you identify potential physicians or individuals conducting research within your walls. It also binds them and makes them realize that their clinical privileges are tied to their compliance with the research policies, including research billing compliance.

Second, communicate with the investigator team or the principal investigator at the completion of the coverage analysis process. Acknowledgment shares the final coverage analysis with the investigator. It also identifies which services called out in the protocol will be charged to the study vs. third-party payers.

Third, we should not ask clinicians to make billing determinations after the fact. We do not ask them to do so in their clinical care pathways, so we should not do it in research. That is what the coverage analysis is there for, and that is why we have a research billing compliance team. Let that process work.

Q: Sponsors and sites sometimes disagree whether specific labs, EKGs, etc., can be billed to insurance as clinically appropriate monitoring of the effects of the item or service per NCD 310.1 or should be paid for by the sponsor. How do you navigate that decision?

A: It is common to see the sponsor disagree or push back on site billing designations, sometimes due to the sponsor's lack of knowledge regarding what Medicare will pay for vs. standard of care. The sponsor may think that chemistry is standard of care, but the chemistry item in the protocol includes more than a comprehensive metabolic panel. Additional tests such as LDH or magnesium may not have side effects that warrant those tests.

Look for prescribing information if available; some drug labels recommend specific tests and frequencies to monitor certain side effects. If a study drug does not have prescribing information, look to the ICF or the investigator brochure to determine if there is a side effect that warrants a test. Ultimately, the site is responsible for billing and billing regulations. Sites should push back on the sponsor if they

are asking to change a billing designation. If you provide the context for the research determination, most sponsors are reasonable.

Q: How do you successfully negotiate clinical research time allocated to PI consenting, CRC consent, prep or data entry if the sponsor insists on less? When should items be sent to invoicing vs. budget if negotiable?

A: As far as PI and coordinator costs, we typically document costs based on hourly rates and time estimations. Some sponsors will not agree to PI oversight as a line item, so we cover the costs within other line items in the budget. It depends on the site's internal requirements and what the sponsor is willing to do.

For invoicing, we mark items if they are procedure alternatives; a CT or an MRI vs. an echo or a MUGA. It depends on your site's resources to invoice and follow up. You may want to embed some variable items in the per-patient costs, e.g., pregnancy tests or smaller items. Most sites prefer to have any item required for all patients listed in the per-patient budget instead of being invoiceable. For big-ticket items or those that might vary in costs, e.g., a scan or a biopsy, the sponsor usually prefers those to be invoiceable.

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