

Frequently Asked Questions:

1. **Why do we have to do this?**

Several academic medical centers have been fined millions of dollars for inappropriately billing the Medicare program, state Medicaid programs, and/or commercial health insurance companies for services provided to clinical study participants. The biggest issue with past settlements and fines involved double billing: billing Medicare or another insurer for services for which a sponsor has already paid (e.g., billing Medicare for an x-ray which was already funded as part of the budget with the sponsor).

2. **Does the new policy apply to my study?**

If your study is enrolling human subjects who will receive some sort of medical items or services, such as office visits, labs, drugs, etc.), then this policy applies to your study. The funding source (industry sponsor, federal grant, foundation grant, or other source) is irrelevant. If your participants have already received any and all medical services and you are no longer enrolling new participants, then you do not have to create a billing grid or provide these forms to UT Medicine.

This policy does not apply to a study that does not have human subjects, or those studies consisting of only surveys, chart reviews, or limited data sets.

3. **Do I have to comply with these requirements even if I do not plan to bill Medicare?**

Yes. Many commercial insurance companies also follow the Medicare rules/guidelines. Also be aware that in order to avoid inadvertent double billing you must provide clear communication that the research account must be billed and not a third party payor/participant.

4. **What do we have to do?**

Research teams must communicate to the billing office who the appropriate payor (the sponsor or insurance/participant) is for each service. This new policy requires research teams to begin using billing grids and UT Medicine forms to communicate the necessary information to UT Medicine.

5. **Will more information/guidance/processes be coming out soon?**

Yes! Ensuring the appropriate party is billed for a service requires communication of specific information to the appropriate offices using standard processes and forms. Additional guidance and information will be out later this year with regards to interacting with both UT Medicine and our affiliates, such as UHS.

6. **I don't really understand what is required of me, or how to create a billing grid. Is there anyone who can help me?**

Yes, the OCR would be glad to help you! Call 567-0651 and ask to speak with Kay Perry or Ché Kelly, or you can reach them directly at perryk3@uthscsa.edu/567-0452 or che@uthscsa.edu/567-0653.

7. **Can you also help me with budgeting for a clinical trial?**

Yes! The OCR can assist you with developing budgets. Good budgeting is a precursor to creating the billing grid. Additionally, online training on clinical trial budgeting will be available in the summer of 2009 (it will be accessed via the Knowledge Center). For budgeting assistance, contact Ché Kelly at che@uthscsa.edu or 567-0651 (main office)/567-0653 (direct).