MOFFITT CANCER CENTER

December 6, 2021

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-9908-IFC
P.O. Box 8010
Baltimore, MD 21244–1850
Attention: RIN 0938-AU62

Re: CMS–9908–IFC - Requirements Related to Surprise Billing; Part II

To Whom It May Concern:

Moffitt Cancer Center ("Moffitt") appreciates this opportunity to comment on the interim final rule ("IFR") that was jointly released on September 30, 2021 by the Departments of Health and Human Services ("HHS"), Labor, Treasury and Office of Personnel Management (collectively referred to as "HHS" for purposes of this letter) to implement certain provisions of the No Surprises Act (the "Act"). Our comments focus on the requirements under the IFR for hospitals to provide good faith estimates of health care items and services for uninsured or self-pay individuals and the associated patient-provider dispute resolution process.

Moffitt is the only National Cancer Institute-designated Comprehensive Cancer Center based in Florida. Our sole mission is to contribute to the prevention and cure of cancer. We provide cancer care to more than 69,000 individual patients each year, a large percentage of whom are Medicare beneficiaries. We also maintain a wide portfolio of research so that we might help elevate the standard of care for all those diagnosed with cancer. As described in greater detail below, while Moffitt supports the goal of increasing the availability of meaningful price and quality information to better equip patients to make informed health care decisions, the requirements under the IFR for hospitals to provide good faith estimates to uninsured or self-pay individuals pose substantial operational challenges, which in some instances may create barriers to accessing cancer care.

Complexity of Estimating Costs for Specialty Oncology Care

The requirement under the IFR that hospitals provide uninsured or self-pay patients with a good faith estimate of costs poses unique challenges for specialty oncology care. This is because estimating the costs of specialty oncology care is difficult due to significant variation in those costs based on the unique circumstances of each individual patient, which often evolve significantly during a particular course of treatment.

More specifically, cancer surgeries often vary from what was originally planned based on what the physician observes during the surgery, which can greatly affect the cost. For example, a laparoscopic surgery to remove uterine cancer can become a radical total laparoscopic hysterectomy depending on the observed disease state once the surgeon is inside of the uterus. Additionally, the actual procedure can vary from what was originally planned (and for which costs were estimated) due to normal disease progression between the time of scheduling and the time of surgery. For example, neoadjuvant chemotherapy and/or radiation therapy is often given to a patient with pancreatic adenocarcinoma before surgery. This pre-surgical intervention may impact the surgery that is ultimately performed if it is effective at reducing, or at least slowing progress of, the disease. On the other hand, if the pre-surgery chemo and/or radiation is unsuccessful, the progress of the disease may require a more extensive surgery. Furthermore, sometimes surgeries are exploratory by nature, which may result in the patient undergoing additional, simultaneous procedures that were not anticipated in the initial estimate provided.

In addition, it is extremely difficult for oncology providers to provide an up-front estimate of the pharmaceuticals that may be used in the course of cancer treatment. The medications used by this patient population is highly personalized to the individual patient's condition, comorbidity, and disease type and stage, and thus there are no specific benchmarks that an oncology provider can refer to in order to provide a good faith estimate of the drug costs (particularly within a $400.00 range). Additionally, such drugs may ultimately be subject to manufacturer discounts as described below, which is generally not known up-front and requires back-and-forth with the manufacturer that can take time.

All of these factors make it very difficult to provide a good faith estimate of the costs of specialty oncology care upfront.

Good-Faith Estimate Requirements Are Unduly Burdensome

We believe that the window of time given to complete the good faith estimate is unreasonable and unduly burdensome, particularly given the complexity of accurately estimating the cost of cancer care services as described above. Specifically, pursuant to the IFR, a convening facility or provider is required to provide an uninsured (or self-pay) patient with a good faith estimate of expected charges upon request or upon scheduling an item or service, within the following timeframes:

- No later than one business day after the date of scheduling when a primary item or service is scheduled at least three business days before the date of furnishing;
- No later than three business days after the date of scheduling when a primary item or service is scheduled at least ten business days before the date of furnishing; and
- No later than three business days after the date of the request when a good faith estimate is requested by an individual.

In addition, the IFR requires convening facilities and providers to coordinate with co-providers and co-facilities to obtain all information relevant to the items or services expected to be provided by such co-providers and co-facilities, in order for such information to be incorporated into the good faith estimate ultimately provided by the convening facilities and providers. Thus, the burden of ensuring that the good faith estimate provided to individuals is accurate, comprehensive, and timely rests with convening facilities and providers, who have, in some instances, only one business day to complete these tasks. This is not only an operational burden (particularly for high-volume convening facilities and providers who may not have the ability to compile all of the required information in one business day), but it also imposes a financial burden on such facilities and providers to update their technology systems to efficiently communicate and share information with co-facilities and providers, and to potentially hire additional employees to assist in carrying out these responsibilities.

Compounding these challenges is the fact that under the IFR, hospitals are required to be very precise in the good faith estimates they provide. If the actual billed charges are "substantially in excess" of the expected charges as identified in the good faith estimate, the patient is eligible to initiate a patient-provider dispute resolution process. The IFR defines the term "substantially in excess" to mean an amount that is at least $400.00 more than the total amount of expected charges for the provider or facility listed on the good faith estimate. In oncology care, it is routine for patient accounts to accrue large amounts of charges over several months. Relative to the total costs accrued in most cancer care, a $400.00 variance may be an extremely small percentage. For this reason, the $400.00 cap affords insufficient latitude to account for circumstances that commonly arise during the course of cancer care, but are not necessarily considered "unanticipated" or "unforeseen" such that they would be exempt from the good faith estimate requirement. This level of precision will also lengthen the amount of time it takes to prepare good faith estimates, rendering the time frame set forth in the IFR to prepare such estimates unreasonable.

Additionally, the IFR may create a barrier to pursuing cancer care for some patients by incentivizing oncology providers to provide estimates that are on the upper end of the range of charges that could be anticipated as a way to avoid the dispute resolution process. Higher estimates may discourage some uninsured and self-pay patients from pursuing care, even when their actual charges would likely have turned out to be much lower than the estimates. Moffitt's standard practice of obtaining free drug replacement on behalf of patients is a concrete example of how our good faith estimate might need to be drastically inflated beyond the actual charges. For many patients, chemotherapy drugs are covered by the manufacturer. Most often, however, we would not be certain within the three-day window whether a manufacturer will offer this benefit, so this cost would be included in the good faith estimate and might deter patients from pursuing care.

In light of the operational difficulties described above, we request that HHS consider increasing the flexibilities associated with the IFR's requirement to provide a good faith estimate, particularly for certain types of specialty care providers, such as oncology providers, and/or for specific types of procedures, such as exploratory procedures. HHS should consider extending the period within which a good faith estimate must be provided to an individual from one to three business days, and only if the individual schedules the appointment at least five days in advance. This will enable a convening provider or facility greater ability to communicate with co-providers and facilities, as well as a better opportunity to evaluate the particular individual's condition and anticipated treatment in relation to the expected charges. Further, if an individual does not have a scheduled appointment but simply requests a good faith estimate, a provider or facility should have five business days to compile a good faith estimate, as there is decreased urgency for a patient without any scheduled appointment.

Along those lines, HHS should also extend flexibility to estimation of the charges themselves. Specifically, HHS should allow a convening provider or facility to provide a range of potential charges in the good faith estimate that are possible based on the intended procedure and potential alternatives or additional procedures that may likely be provided based on the patient's diagnosis, for which the $400.00 cap would only apply to the extent the actual charges exceeded the higher end of the estimated range of charges.

In the alternative, for certain specialty care providers or certain types of procedures, HHS could consider giving providers and facilities latitude to provide a reasonable, good faith estimate based on the anticipated procedures, but incorporate a disclaimer that based on the nature of the care or procedure, the actual charges may vary depending on the diagnosis and progression of the patient's condition, for which the $400.00 cap and patient-provider dispute process would not apply, similar to IFR's treatment of unanticipated, unforeseen items or services that are not reasonably expected. As currently drafted in the IFR, although certain items or services may be unanticipated or unforeseen, they would not necessarily fall into this exemption from the good faith estimate requirement to the extent they are reasonably expected based on the scope of the specialty care or exploratory procedure. Instead, the IFR contemplates this scenario only with respect to providers who are already partaking in the patient-provider dispute resolution process.[1] This will result in providers constantly finding themselves having to partake in the dispute resolution process and defending the medical necessity of procedures on the back-end, rather than enabling providers to notify patients of this possibility and avoiding the dispute resolution on the front-end.

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[1] 86 Fed. Reg. 55980, 56037-38 (Oct. 7, 2021) ("In cases where changes in the underlying circumstances occur during treatment and would reasonably result in higher than expected charges, the SDR entity may consider additional factors that support charges for medically necessary items or services."). This requires providers to demonstrate medical necessity to the SDR entity by providing documentation detailing any change in circumstances, how that change resulted in a higher billed charge than the expected charge for the item or service in the good faith estimate, and why the billed charge reflects the cost of a medically necessary item or service.

The IFR also requires providers to include in the good faith estimate a list of applicable diagnosis codes and expected service codes. Similar to the reasons cited above, HHS should consider removing these requirements particularly with respect to exploratory procedures, which are intended, at least in part, to assist the provider in diagnosing a patient (which may result in a further, necessary service).

In tandem with the above-referenced modifications, HHS should consider replacing the $400.00 threshold with a percentage by which actual charges cannot exceed a good faith estimate. This is necessary in order to scale the amount of charges that constitutes "substantially in excess" of the estimate. While $400.00 may be the appropriate threshold for certain lower-cost services, it represents an extremely small margin for higher-cost services, such as specialty oncology care, and in those instances, would be inconsistent with the statutory standard (e.g., for a $100,000 treatment, $400 is only .4%, which is not "substantially in excess" of the treatment cost based on a plain language reading).

Thank you for the opportunity to provide comment.

Sincerely,

Joanna C. Weiss

Joanna Weiss
Vice President, Finance