

(Insert Date)

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1694-P  
P.O. Box 8011  
Baltimore, MD 21244-1850

Re: Comments on the FY 2020 IPPS Proposed Rule Designation [insert specific IPPS rule for comment]

To Whom We May Address:

Thank you for allowing us the opportunity to submit comments regarding the proposed IPPS rules for FY 2020. (Insert name of institution here) is grateful for the efforts of your organization to improve the nation's health, and for your willingness to review additional information during the public comment period before issuing your final rules. It's clear that great time and effort was invested in the proposed rule, and we appreciate and recognize this work of public service.

(Specific concern: Here is where you freelance and go to town! Everyone will have their own list of specific issues to comment upon, be it morbid obesity, end-stage renal disease, pressure ulcers, MI's, blood loss anemia, transplant status, etc. The biggest concerns will differ between institutions based on the populations they serve. We encourage you to choose you five or six "big-ticket" items and summarize each in a brief **\*\*no longer than 2 pages\*\*** letter, taking care to emphasize the clinical justification, impact on future use, social impact, age impact, healthcare access impact, etc. for why something should or should not be re-designated and as CC, MCC, or Non-CC. Think about things that CMS may not have had access to or might not have considered as part of the impact of the change. It's important that this not be about the \$\$\$\$. Site clinical evidence research when available.)

*Here is an example of the comment letter that was sent in to reverse the proposed changes in ECMO from last year's IPPS proposed rules:*

*The new IPPS rules indicate that ECMO will now be broken down into two categories: centrally inserted ECMO and peripherally inserted ECMO. Centrally inserted ECMO will remain unchanged. It will retain its status as an OR procedure which will sequence it as the principal MS-DRG and its reimbursement weight will remain the same. Peripherally inserted ECMO will now be assigned a non-OR status and will no longer sequence as the principal MS-DRG. The result of this change means that peripherally inserted ECMO will be reimbursed at a much lower relative weight. While we agree with the stipulation that ECMO can be instituted via either centrally inserted catheters or peripherally inserted catheters, we do not think that this should be the sole indicator to determine how ECMO should be classified and reimbursed. We would like to discuss other aspects of ECMO that should be considered when assessing MS-DRG classification and reimbursement weights: patient demographics, resource utilization and impact on future use.*

*One of the first things that we did when we were informed about the recommended changes to ECMO classification and reimbursement was to review the records of all the patients that received ECMO therapy here at \*\*\*\*\* in 2018. We found exactly what you had forecasted: the majority of the patients*

*receiving ECMO did receive the therapy via peripherally inserted catheters. But we also found some other variable that we would like to share with you:*

- The average age of the adult ECMO patient at \*\*\*\*\* is 45. If we add in the \*\*\*\*\* pediatric ECMO population to this demographic, the average age of the ECMO patient population drops even further. Given that the general age of the ECMO population is < 65, we are concerned that CMS may not have had access to enough patient data to obtain an accurate description of the differences between centrally inserted ECMO and peripherally inserted ECMO.*
- You are correct in your assessment that centrally inserted ECMO is done predominantly in the OR. But the majority of our peripherally inserted ECMO is also performed in the OR. This is out of necessity not convenience. The insertion of ECMO, whether central or peripheral, requires the presence of a cardiothoracic surgeon, a first assistant, an anesthesiologist, a perfusionist and number of support personnel that include RNs as well as various technicians.*
- Insertion of peripheral ECMO at the bedside is never by choice. Circumstances have evolved that require the emergent initiation of ECMO in order to prevent certain death. The patient is either too unstable to move or time does not allow for the luxury of moving the patient to OR. When ECMO is inserted at the bedside, we move the OR into the room. Every team member that is needed to insert ECMO in OR is needed to insert ECMO at the bedside. That means insertion of bedside peripheral ECMO requires a cardiothoracic surgeon, a first assistant, an anesthesiologist, a perfusionist and a number of RNs and technicians.*
- The cost of ECMO is not incurred due to the use of the OR. The cost of ECMO is incurred in the daily resources expended in maintaining the ECMO therapy. We have a baseline of personnel available for all patient care in our CVICU: intensivists, nurses, respiratory therapists, physical therapists and occupational therapists. The ECMO patient requires additional personnel. The hospital must supply an additional nurse to the unit in order to provide one to one patient care for the complex ECMO patient. The hospital must assigned a perfusionist outside of the OR to assess the ECMO patient at least every two hours around the clock and to travel with the patient as needed for testing. If the ECMO patient is required to travel off the floor for a test or procedure, the patient is accompanied by 2 RNs, a CTS fellow or intensivist, a perfusionist, a respiratory therapist and technician.*

*These are just some of the ways the adult patients with centrally inserted ECMO are similar to patients with peripherally inserted ECMO. Our review of adult ECMO patient records did not produce any distinction between these two patient populations that would justify a change in ECMO classification and reimbursement.*

*\*\*\*\*\* also uses ECMO in our pediatric units. This therapy has proved to be an effective lifesaving intervention for neonates and children. ECMO cannulation in this population is almost always performed in the PICU with the entire OR team in attendance regardless of insertion site. There are no percutaneous devices available for pediatric peripheral cannulation. We are required to perform a surgical cut down in order to access a vessel large enough to support peripheral insertion of the larger cannulas. This means that all cost and personnel support are the same regardless of peripheral or central cannulation in the neonatal/pediatric population.*

*Finally, we are concerned that the proposed changes in ECMO classification and reimbursement disproportionately impacts tertiary and quaternary centers who provide care at the highest acuity level for the various regions of the U.S. These care centers have seen an increased utilization of ECMO over the last few decades with an associated improvement in mortality and morbidity in the younger adult patient population. One example of this is early use of ECMO for out-of-hospital cardiac arrest [1,2] which has demonstrated an improved functionally favorable patient survival rate. Other examples would*

*be the use of ECMO to treat ARDS in the influenza and sepsis patient populations as well as the use of ECMO in providing time for the solid organ malignancy patient to respond to therapy. We believe that these improve outcomes justify the use of ECMO as a viable therapy option for the critically ill patient. Most of these patients have no other treatment option at the time of ECMO initiation [3]. We also believe that changing the ECMO MS-DRG would discourage ECMO care centers from expanding ECMO use and improving ECMO technology.*

Thank you for the opportunity to comment on the proposed FY 2020 IPPS rule. On behalf of (insert your institution here), we look forward to your review of our comments, and to our future participation in the rule-making process. We greatly appreciate your time and consideration.

Sincerely,

(Insert Name, Title, Institution)