ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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June 8, 2015

Shari M. Ling, M.D.
Deputy Chief Medical Officer
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Form CMS-2728-U3 Revisions

Dear Dr. Ling:

On behalf of the American Society of Nephrology (ASN), I write to raise serious concerns about the Centers for Medicare and Medicaid Services' (CMS's) revisions planned for Form CMS-2728-U3 (07/14), otherwise known as the 2728 and the ESRD Medical Evidence Form, scheduled for implementation on Thursday, October 1, 2015. As the leading kidney health professional society in the world with more than 15,000 members from 114 countries (including approximately 90% of the nephrologists in the United States), ASN is dedicated to providing the highest quality of care for patients with kidney disease.

Form 2728 serves multiple purposes, including:

1. Certifying that a person has End-Stage Renal Disease (ESRD).
2. Enumerating key characteristics for the ESRD population so as to better understand who is being served by this benefit.

Identifying the primary cause of kidney failure is crucial for determining where clinical and research resources should be allocated to reduce the burden of ESRD, and therefore is of public health importance.

The information collected by Form 2728 is publically available through the US Renal Data System (USRDS). The ability to examine trends over time, including the causes of ESRD, is very useful for clinical, research, and policy purposes. Unfortunately, the planned revision to Form 2728 includes a complex five-page condition classification system for diagnosing the primary cause of ESRD that will make this purpose increasingly onerous for clinicians to complete.

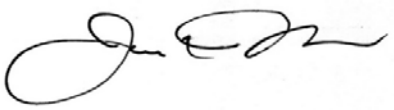
In theory, every nephrologist will take the time to review all the condition codes to select which code best identifies the cause of kidney disease. The reality is that this process will not occur with the rigor necessary to generate quality data. Moreover, a number of common causes of ESRD, including obstruction and atheroembolic disease, are no longer included on the form.

In addition, classification of other causes of kidney failure becomes more complex. For example, disease diagnoses like IgA nephropathy, which is the most common glomerulonephritis in the world, and anti-glomerular basement membrane disease, a cause of rapidly progressive glomerulonephritis, are replaced by far less specific pathology descriptors that will be significantly less informative for users of these data and add to the complexity of accurately entering patient data by the nephrologist. Light chain disorders, heavy chain disorders, and other monoclonal etiologies of kidney failure, which are increasingly common causes of ESRD, have been lumped into "Multiple myeloma not having achieved remission." In contrast, there are six codes categorizing Niemann-Pick Disease, a very rare condition that is not associated with kidney failure. There are also 76 codes that address gout, another exceptionally unusual cause of ESRD.

An important part of public health surveillance and dialysis practice and research, Form 2728 is an important element of care for beneficiaries with kidney failure. ASN urges CMS to postpone the planned revisions to the form until the agency incorporates the input of the kidney community to help refine the classification system such that the data will be adequately aligned with ICD-10, while remaining sufficiently detailed and economical to serve the mission of facilitating dialysis care.

Thank you for considering these serious concerns about CMS's revisions planned for Form CMS-2728-U3 (07/14), otherwise known as the 2728 and the ESRD Medical Evidence Form. To discuss this letter, ASN's issues with the planned revisions, or the society, please contact ASN Manager of Policy and Government Affairs Rachel N. Meyer at rmeyer@asn-online.org or at (202) 640-4659.

Sincerely,



Jonathan Himmelfarb, MD, FASN
President

cc: Rachel N. Meyer
John R. Sedor, MD, FASN