

June 25, 2013

Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services

**RE: CMS–1599–P Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long- Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation**

Dear Ms. Tavenner:

Consumers Union, the advocacy and policy arm of *Consumer Reports*, has signed onto other comments submitted by the Consumer-Purchaser Disclosure Project and we refer you to those for our comprehensive comments regarding the proposed regulations. However, we would like to further comment on the issue of validation of hospital-acquired infection data that is submitted via the CDC National Healthcare Safety Network (NHSN) and provided to the public on the Hospital Compare website.

We appreciate that CMS is planning validation activities for all of the hospital infection measures but are concerned that the process currently used, and proposed, is not the most effective policy for producing accurate reports on this particular type of patient harm. In our opinion, effective validation of hospital-acquired infections is an essential component of eliminating them.

Ten years ago, CU's Safe Patient Project began initiating legislation in the states to require hospital infection reporting. We believe that public transparency is a key factor in preventing future infections and ensuring that consumers seeking help in making informed health care choices have access to accurate information. With our national network of patient safety advocates, many who have been infected or lost a loved to infection, we have worked extensively to implement these laws in most of the 30 states that have these requirements. As we have done this, we have come to understand that thorough validation is important for many reasons.

There is much evidence that hospital self-reports of medical harm inaccurately reflect the actual harm that is taking place, and we have certainly seen this in hospital infection reporting. Numerous states have conducted validation, including chart reviews, and have discovered many errors and omissions. Most of these results are included in public reports by the states involved. So, we know from experience that a thorough validation process is necessary to accurately reflect a hospital's infection rate.

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Another important role of state validation activities has been that of educating the staff documenting infections at the hospital level about how to use the NHSN system correctly and even more important, how to use this system as a surveillance tool in their daily prevention activities. When we began this work ten years ago, we imagined that hospitals were hiding their infection rates from the public, but we quickly discovered they were not. They simply did not know what their infection rates were. And even today, most hospitals only know their rates of the types of infections that are connected to statutorily required reporting. As the NHSN system rolled out at the same time of state mandates being passed, we were presented with a unique opportunity to ensure that every hospital had a system to track infections. It was also evident that many hospitals did not have adequate number of trained staff for infection prevention. Addressing these two issues alone was a remarkable accomplishment that continues to affect the safety of hospital patients throughout the country. State health department staff and NHSN staff communicated and trained hospital staff on methods of tracking infections and thus enabled them to improve prevention at their facilities. We strongly believe that these activities have saved countless lives.

While we recognize that CMS has many quality and safety measures to validate for public reports and that having a uniform method for validating all measures seems most efficient. However, we ask that you consider that the human devastation and cost caused by hospital-acquired infections warrants special attention. Nearly two million hospital patients are infected each year and almost 100,000 of them die from those infections. The annual cost for *hospital* care alone is as much as \$45 billion – that does not include physician care, medications, wound care, or physical therapy.

We think thoroughly validating hospital reported infections should be a component of a comprehensive national effort to prevent those infections. A small investment by CMS in state level staff to go into hospitals to check the accuracy of this data is critical to the many prevention efforts currently funded by the federal government. This will lead to confidence in the outcomes of these programs – the public deserves to see factual results.

Finally, we have great concerns that the methods currently used by CMS to validate infection data (and those being proposed to use on future infection measures) fail to yield accurate information and allow for easy manipulation by those hospitals that wish to hide the true picture of the safety of their care. Specifically, assessing the risk of infection at a particular hospital requires a calculation of the rate of infection, which includes both a numerator and a denominator. As anyone with basic math skills knows, the rate can be significantly altered by variation in either of these components. It is our understanding that CMS is only validating data for the numerator (the number of infections) without validating the denominator (the number of patients at risk of infection). Those of us who have followed hospital infection reporting for years know that collection of denominator data has been particularly challenging for hospitals. Thus, determining the accuracy of the denominator is critical for any validation process used by CMS; failing to do so renders validation of the numerator virtually a waste of time and resources. Further, we have concerns that the minimal number of hospitals involved in the CMS validation process and the extremely minimal number of records that those hospitals must send for validation fail to provide a sufficient check on accuracy.

We urge CMS to take a longer view on the value of establishing a strong validation program for hospital-acquired infections. A process that engages state health agency workers who interact

directly with the hospitals provides multiple benefits that are more than warranted by the serious damage done to patients and the health care system due to hospital-acquired infections. If CMS chooses not to support a state-level system, we strongly recommend that the current and proposed validation process add validation of both the number of infections reported and the number of patients at risk of infection.

Sincerely,

A handwritten signature in black ink, reading "Lisa McGiffert". The signature is written in a cursive style with a large initial "L" and "M".

Lisa McGiffert  
Consumers Union, Safe Patient Project  
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