Consumers Union
Nonprofit Publisher of Consumer Reports

Stop Hospital Infections.org
A Project of Consumers Union

June 13, 2008

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1390-P
P.O. Box
Baltimore, Maryland 21244-1850

Comments of Consumers Union of the U.S. Inc.
to the Centers for Medicare and Medicaid Services
"Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians
PROPOSED RULE
Docket No. CMS-2008-0039-0006"
CMS-1390-P

Dear CMS:

Consumers Union (CU), the nonprofit publisher of *Consumer Reports*,[1] submits the following comments in response to the Centers for Medicare and Medicaid Services (CMS) Proposed Rule (PR) "Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates." Generally, we strongly support the proactive nature of these proposals that significantly expand the federal government's effort to improve health care outcomes through payment adjustments to health care providers and public disclosure of health care quality and safety measures.

[1] Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of Consumer Reports, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, Consumer Reports with approximately 4.5 million paid circulation, regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

For the past five years, Consumers Union's Stop Hospital Infection Campaign has worked to raise public awareness of and to put a human face on the problem of hospital-acquired infections, which previously were viewed as unavoidable. We have been strong advocates for public disclosure of hospital-acquired infection rates at the state level. Now 22 states require hospitals to disclose certain types of infection rates and several Congressional bills have been introduced to make this a national requirement. We have also advocated for the screening of incoming patients for methicillin-resistant *Staphylococcus aureus* (MRSA) and the use of specific precautions for patients colonized with the bacteria to prevent the spread of MRSA to other patients. Three states have adopted such requirements, many other states are considering legislation to do so, and several Congressional bills would require hospitals to use this life-saving technique.[2]

Our work includes collaborating with local individuals and organizations to pass legislation, educate the public, and implement these laws in ways that serve the public. Most of these advocates have survived or lost a loved one to preventable infections. They have educated themselves, become experts on the subject, and are fierce advocates for stopping infections and other hospital-acquired conditions. Additionally, over 2,000 people have shared their hospital infection experiences with us, and they have played the most significant role in turning the tide from complacency to the zero tolerance of infections that many hospitals and leaders in infection control are now embracing.

Public disclosure of health care safety and quality measurements, as well as payment structures that encourage prevention of hospital-acquired conditions are essential tools to stop them from happening. Consumers Union believes these initiatives have the potential for saving tens of thousands of lives and billions of dollars in the Medicare system. Also, as we saw with the adoption of the initial CMS no-payment regulations, other payers are beginning to follow suit, extending these policies beyond the Medicare population.

PREVENTABLE HOSPITAL-ACQUIRED CONDITIONS (HACS), INCLUDING INFECTIONS

Consumers Union applauds CMS for significantly expanding the list of hospital-acquired conditions for which Medicare will not reimburse health care providers. We support inclusion of all nine new conditions[3] and are pleased to

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[2] For more information about federal and state legislation, state laws, and state reports, go to http://www.consumersunion.org/campaigns/stophospitalinfections/learn.html

[3] surgical site infections following elective procedures of total knee replacemnt, laparoscopic gastric bypass and gastroenterostomy, and ligation and stripping of varicose veins; legionnaires' disease; glycemic control for diabetic ketoacidosis, nonketotic hyperosmolar coma, diabetic coma, and hypoglycemic coma; iatrogenic pneumothorax; delirium; ventilator-associated pneumonia; deep vein thrombosis/pulmonary embolism; staphylococcus aureus septicemia; and clostridium difficile associated disease.

see additional infection-related conditions on the list for 2009. We also support the modifications proposed for the conditions to begin on October 1, 2008 – specifically, including an omitted code relating to a foreign object retained after surgery and modifying the HACs related to pressure ulcers using newly approved coding changes.

We have the following specific comments about certain of these measures:

Surgical site infections. It is a significant step to include the list of surgical site infections following elective procedures (specifically, total knee replacement, laparoscopic gastric bypass and gastroenterostomy, and ligation and stripping of varicose veins) and we fully support these additions. However, we strongly recommend to add hip replacement to the 2009 list – it is an obvious omission in light of the significant number of procedures being done on Medicare patients. A study reviewing 2003 nationwide U.S. data to determine the incidences, factors, and short-term outcomes of primary total, partial, and revision hip replacements found about a third of a million such hip procedures.[4] Rates of readmission within 90 days ran between 9% for total replacement to 21% for partial replacement. Clearly, these are very serious operations in which infections occur too often and should be included on the list for 2009. Further, the program should work toward applying the non-payment rule to infections following all surgery.

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Further, the program should work toward applying the no-payment rule to infections following all surgery, especially all elective surgery.

Ventilator-associated pneumonia (VAP). We strongly support inclusion of this condition that affects almost 31,000 Medicare patients. VAP is one of the more common types of hospital-acquired infections, is among the deadliest of infections and is preventable. The Institute for Healthcare Improvement's initial 100,000 Lives Campaign demonstrated that hospitals aiming to consistently use prevention techniques could significantly reduce this common hospital-acquired infection.[5] Most states adopting laws to publicly report infection rates have avoided this measure. Missouri, one of the first states to pass such a law, included VAP but the health agency in that state has advocated removing it from the law and this year the measure was changed from the rate of infection to process measures. Several state laws have included VAP for future reporting and Pennsylvania is the only state that currently publishes the rates and incidents of VAP.[6] Clearly, as we have worked around the country, legitimate issues have

[4] Zhan Chunliu; Kaczmarek Ronald; Loyo-Berrios Nilsa; Sangl Judith; Bright Roselie A., "Incidence and short-term outcomes of primary and revision hip replacement in the United States," J Bone Joint Surg Am. 2007 Mar; 89(3): 526-33.

[5] http://www.ihi.org/IHI/Results/SuccessHeadlines/

[6] http://www.phc4.org/reports/hai/06/

been raised regarding the complexity and unworkability of the current CDC VAP definition. When the NQF recently endorsed various infection related measures, it called upon CDC to move quickly to revise its VAP definition.[7] So, public reporting of VAP rates is moving very slowly.

Designating VAP as a hospital-acquired condition provides the opportunity to address this issue through an alternative route to public disclosure, i.e., payment disincentives. Just as the initial CMS no-payment list's inclusion of catheter associated urinary tract infections has generated activity among hospitals to put prevention practices in place before October 1, 2008,[8] we believe including VAP in 2009 will lead to similar implementation of well recognized VAP prevention practices.

Hospital-acquired infections. We strongly support inclusion of hospital-acquired Clostridium difficile associated disease (CDAD) infections and *Staphylococcus aureus* septicemia on the list for 2009. There are long-standing prevention techniques for infections caused by these bacteria that are too rarely followed, such as strict hand hygiene and thorough environmental cleaning. We believe adding CDAD infections to the non-payment list will result in a significant increased use of these techniques. Hospitals have the tools; we don't need more research, we just need hospitals and other health care providers to use these practices that have already proved to work.

Recent reports on CDAD reveal that it is a rising superbug that is wreaking havoc in our nation's hospitals. The Agency for Healthcare Research and Quality recently issued a report revealing that the "number of hospital discharges with CDAD more than doubled from 2001 to 2005, a trend that was considerably steeper than the prior 8-year period, during which the number of cases increased by 74 percent hospital discharges with CDAD increased from approximately 85,700 to 148,900 per year from 1993-2001...CDAD primarily affects elderly patients—over two-thirds of patients with CDAD were 65 years and older.9 It is extremely important that we get control of this terrible condition now – it is already too late for so many elder patients and is now also attacking younger patients.

Methicillin-resistant *Staphylococcus aureus* (MRSA). We strongly disagree with the decision to leave hospital-acquired MRSA infections off of the 2009 non-payment list and urge CMS to add them as soon as the new MRSA-related codes are adopted.

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[7] http://www.qualityforum.org/publications/reports/hai.asp, VAP discussion page 16.

[8] At the February 2008 meeting of the CDC HICPAC, members discussed a flurry of activities ranging from establishing "avoidance" policies so catheters are used only when necessary to creating reminder systems for physicians to order timely removal of urinary catheters. Hospitals have known for decades that prolonged and inappropriate use of catheters was the source of hospital-acquired UTIs, but no real change began until the CMS non-payment rule was adopted.

9 Agency for Healthcare Research and Quality, "Clostridium Difficile-Associated Disease in U.S. Hospitals, 1993–2005," Anne Elixhauser, Ph.D. and Michael Jhung, M.D., M.P.H.; April, 2008.

We have concerns that the information presented in the CMS proposal on MRSA is incorrect and could mislead the public. According to the study cited in the proposal, less than 1 percent of the general population are carriers of the MRSA bug, instead of 32.4 percent as indicated in the proposal – 32.4 percent is the ratio of people who are colonized with *Staphylococcus aureus*.[10] Further, the proposal states, "As we noted in the FY 2008 IPPS final rule with comment period, colonization by MRSA is not a reasonably preventable HAC according to the current evidence-based guidelines; therefore, MRSA does not meet the reasonably preventable statutory criterion for an HAC." The hospital-acquired condition that CMS needs to withhold payment for is hospital-acquired MRSA ***infections***, not MRSA ***colonization***. And MRSA infections are very definitely preventable in the hospital setting. We know of no one advocating to label MRSA colonization a hospital-acquired condition. MRSA infections are very definitely preventable in the hospital setting. We recognize that coding has been a problem in that the existing codes for MRSA do not distinguish between infections and colonization. However, the new codes currently moving through the adoption process should address this issue.

Even though the infection-related conditions on the current and proposed list will no doubt pick up some MRSA infections, we urge CMS to add *MRSA hospital-acquired infections* to the list as soon as appropriate coding is adopted.

Readmissions. We recommend inclusion of preventable readmissions for the 2009 no-payment policy. The Medicare Payment Advisory Commission (MedPAC) found that almost 18 percent of Medicare hospital patients were readmitted within 30 days of discharge, at a cost of $15 billion to Medicare.[11] Of these, the report estimates that 76 percent of readmissions after 30 days are preventable. Hospitals rarely follow up with patients after discharge and as the MedPAC report indicates, "Hospitals and other providers have not broadly invested in their role in managing the transition." As Consumers Union has worked around the country to implement hospital infection reporting laws, we continually come up against this cultural phenomenon – once a patient leaves the hospital, most hospitals do not follow up to find out if there were any adverse results from those hospitalizations.

Public disclosure of HACs data. We recommend that CMS add a disclosure component to the hospital-acquired conditions data so the public can see which hospitals are subject to withheld payments due to avoidable harm to patients. Further, the proposal calls for ideas beyond payment structure to have an effect on other never events that don't meet the criteria for hospital-acquired

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[10] Kuehnert, M.J., et al.: Prevalence of *Staphylococcusa aureus* Nasal Colonization in the United States, 2001-2002. The Journal of Infectious Disease, January 15, 2006; Vol. 193.

[11] Medicare Payment Advisory Commission, "Report to the Congress: Promoting Greater Efficiency in Medicare," Chapter 5, Payment Policy for inpatient readmissions, June 2007, pp. 103-118.

conditions. We support the program pursuing other methods to decrease the occurrence of other "never events" as endorsed by the National Quality Forum. We strongly recommend that CMS identify these never events using Medicare data and post the number of incidences by hospital. Publishing the incidences of never events is another approach to give hospitals incentives to develop comprehensive plans and processes to prevent them.

Present on admission (POA) coding. POA coding is an important step toward identifying harm that occurs to patients while hospitalized. We also believe it can become a powerful tool to assist health care workers in understanding more completely the needs of their patients, and subsequently improve the quality of care provided. However, we are concerned that hospitals will attempt to game the system in some manner and strongly recommend to select a baseline time period (some time in the past) to identify upcoding trends and to build auditing components into the process.

Financial protection for patients who are the victims of hospital-acquired conditions. Although the CMS initial non-payment policies to go into effect in 2008 clearly prohibit hospitals from billing patients for hospital-acquired conditions, we remain concerned that there are no details regarding how CMS intends to monitor and respond to patients who are in this situation. Further, people covered by Medicare dealing with extensive follow up treatment due to these never events generally must pay significant cost sharing (for future hospitalizations, medications, and other needed treatment that requires them to make co-payments; some have reached the limit of their Medicare coverage due to the needed care following a hospital-acquired condition). There are no financial protections for the significant costs following these serious harmful events. It is not uncommon for people with invasive hospital-acquired infections to need multiple surgeries over a span of many years, extensive medications, expensive medical supplies such as bandages and gauze that must be replaced many times during a single day, wound care, physician care, physical therapy, etc. CMS must address these issues with specific details and should develop an expedited review process for claims from patients who have been harmed by their medical care.

REPORTING HOSPITAL QUALITY DATA FOR ANNUAL PAYMENT UPDATE [412.64(D)(2)]

We strongly support the expansion of the measures required to be reported by hospitals in order to receive the full Medicare payment update. We commend CMS for moving forward to add more measures each year to be publicly reported on the Hospital Compare website. For the proposed measures in 2010, we are pleased to see additional outcome measures and encourage CMS to progressively move away from a focus on process measures toward a focus on outcome

measures. Process measures based on clinical evidence are essential to improving the quality and safety of health care, but ultimately, the public wants to see how often the desired outcomes are being achieved by health care providers.

Additional measures should be included in the 2010 Hospital Compare reports. We recommend including two measures related to hospital-acquired infections from the AHRQ Patient Safety Indicators (PSI) – infections due to medical care and post operative sepsis. Several states publish all of the PSI indicators, including the composite complication index, most notably Florida [add link] and New York [add link]. These would give consumers an overall perspective of infections occurring throughout the hospital.

We also recommend adding hospital-acquired infection rates for surgical site infections and central line associated blood stream infections. Most of the 22 state laws requiring public disclosure of infection rates include these two measures specifically. They have been endorsed by the National Quality Forum and even the Hospital Quality Alliance has recommended including them. The collection of information about infections should be done through the CDC National Healthcare Safety Network (NHSN), as it establishes standardized definitions method for calculating rates and most infection reporting states are using this system already.

Reporting multiple hospitals that share the same provider number as one hospital (p. 473). The proposal states that 5-10 percent of hospitals reported on the Hospital Compare website share Medicare provider numbers and that those under shared numbers are displayed as if they are one facility. This is misleading to the public. We strongly recommend that Hospital Compare information be presented on each individual hospital; multiple hospitals should not report as one hospital. We appreciate the attempt to improve disclosure as proposed in this rule—that is, to at least list the hospitals that are reported under a single provider number, but that is not sufficient. Presenting the information by group, instead of by individual, facility will erode consumer trust in the data.

Racial and Ethnic Data Collection: We echo the comments of The Disclosure Project in supporting the collection of racial and ethnic data to better understand the disturbing trends of racial disparities in health outcomes and treatment. For example, a 2007 study revealing that the rate of serious MRSA infections was significantly greater than previously estimated, also indicated that the incidence rates were consistently higher among blacks compared with whites and recommended future analyses to understand the reasons for this difference in

MRSA infection rates.[12] The study looked at both hospital-acquired and community-acquired MRSA. There are thousands of examples of these disparities and including racial and ethnic information in the growing list of measurements would help health care providers better understand and address such disparities. Disclosure is a powerful tool to bring about change, a tool that needs to be used more frequently in identifying disparities in quality of care.

Respectfully submitted,

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[12] R. Molina Klevens, DDS, MPH, et al, "Invasive Methicillin-Resistant *Staphylococcus aureus* Infections in the United States," Journal of the American Medical Association, 298 (October 17, 2007) 15, pp. 1766, 1769.