Consumers Union
Nonprofit Publisher of Consumer Reports

Stop Hospital Infections.org
A Project of Consumers Union

June 8, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1533-P
P. O. Box 8011
Baltimore, Maryland 21244-1850

RE: **CMS-1533-P**, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and FY 2008 Rates

Dear CMS:

Consumers Union, the independent, non-profit publisher of *Consumer Reports,* appreciates the opportunity to comment on the "Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates."

Our comments will focus on the proposals relating to hospital-acquired infections and other unacceptable adverse events during a hospital admission.

Consumers Union has a history of health care quality work on the state and national levels. Most recently, we are conducting a campaign encouraging legislatures to enact state laws requiring public disclosure of hospital infection rates (http://www.consumersunion.org/campaigns/stophospitalinfections/learn.html). To date, such laws have been considered in 45 states, and 16 states now require hospital-acquired infection rates to be publicly reported. We expect additional states to pass similar laws during this year's legislative sessions. There has been widespread support among consumers and state policymakers for publishing this very basic patient safety measure – the rate at which specific types of infections occur in hospitals – and we see no sign of the demand for this information waning at the state level.

We have undertaken this campaign because these mostly preventable infections affect nearly two million Americans every year. An estimated 100,000 of these patients die each year[1], adding as much as $27.5 billion annually to hospital care alone[2]. For the most

[1] Klevens, R. Monina / Edwards, Jonathan R. / Richards, Chelsey L. / Horan, Teresa C. / Gaynes, Robert P. / Pollock, Daniel A. / Cardo, Denise M; "Estimating Heath Care-Associated Infections and Deaths in U.S. Hospitals, 2002," Public Health Reports, March-April 2007, Vol. 122, pp. 166. http://www.cdc.gov/ncidod/dhqp/pdf/hicpac/infections_deaths.pdf

[2] "In addition to devastating human suffering, the economic costs are shocking. Dr. John A. Jernigan, Chief of Interventions and Evaluations at the Centers for Disease Control and Prevention, estimates that hospital acquired infections add $16,000 to the cost of each hospital patient's care, and pile as much as another

part, the public has been left in the dark about their local hospital's record on infections. Public disclosure of the rate of infection will allow consumers to make more informed health care decisions and will create strong incentives for hospitals to improve care and make infection-prevention a higher priority. The mere fact of disclosure being debated in state houses around the U.S. has stimulated action within hospitals as they realize their infection record could soon be published. **Pennsylvania, in particular, has implemented a comprehensive hospital infection reporting system, and now the Governor has proposed as a logical second step, further actions be taken to reduce and eliminate infections as part of State health insurance reform[3] .** There is much hospitals can do that they are not doing to address this serious and costly problem. Public disclosure is a key component to making that happen.

The data that is being developed in the states with mandatory reporting argues for a similar, aggressive effort at the national level, to ensure that in the near future all residents of the United States will have the information necessary to reward quality hospitals and avoid dangerous hospitals.

Similarly, proposals such as this one (CMS-1533-P) to withhold payment to hospitals for treating the consequences of events that should never happen, will have a significant effect in motivating hospitals to take more aggressive actions to prevent infections and other careless acts that have a devastating effect on patients and our nation's health care system.

Further, it is imperative that the final rule include strong consumer protections to prohibit health care providers from billing patients for any treatment resulting from a hospital-acquired infection or other event that has been identified by CMS for non-payment. Also, there should be a prohibition of any discriminatory practices by the hospital to avoid patients they perceive at risk for infection or other event on the list. If CMS believes these protections are already covered by current Medicare law, references to those specific provisions in existing law would be warranted.

SUMMARY:

Our comments will concentrate on Consumers Union's strong support of:

- the proposal to expand the number of quality measures to be reported as a condition of receiving the full Medicare update, particularly the hospital-acquired infection process and outcomes measures;

$27.5 billion in additional expenses onto the country's healthcare system in hospital costs alone." The MRSA Issue, Emerging, the newsletter of Plexus Institute, Winter 2006, http://www.plexusinstitute.org/NewsEvents/News/show.cfm?id=206

[3] http://www.governor.state.pa.us/governor/cwp/view.asp?a=1113&q=451076&governorNav=|32021| and House Bill 700 http://www.legis.state.pa.us/cfdocs/billinfo/billinfo.cfm?syear=2007&sind=0&body=H&type=B&BN=0700

- the six procedures for which Medicare and beneficiary/consumers will not pay the added cost of hospital acquired infections;

- consideration to add selected surgical site infections and vascular catheter-associated infections for the initial year, followed with strong consideration of ventilator associated pneumonia in 2009;

- and in particular, taking bold steps to address the growing Methicillin-resistant staphylococcus aureus (MRSA) crisis.

While many states have been acting to reduce the rate of hospital-acquired infections (HAI), it is particularly appropriate that Medicare do more in this area given the findings of the Pennsylvania Health Care Cost Containment Council (PHC4) that 76 percent of the infections identified by hospitals as being acquired in their facilities were billed to Medicare and Medicaid, with Medicare paying for most (67%). [4]

SPECIFIC COMMENTS

DRGs: Hospital-Acquired Conditions

We strongly support the aggressive implementation of Section 5001(c) which

> …requires the Secretary to identify, by October 1, 2007, at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines.

For consumers, the key words are 'at least'. We urge CMS to indicate that within a few years time, all the conditions identified and listed will be subject to 5001(c) non-payment, and that CMS will begin a process of adjusting codes and requiring testing for present on admission (POA) conditions (like MRSA), so that all of these quality problems will be addressed in the very near future.

CMS has done an excellent job in listing the many unacceptable events that should never happen and which certainly should not be paid for.

However, while CMS has articulately identified many of the deadly infection problems the nation is facing, the proposed solutions to these problems lack urgency.

The notice stated, "while we have ranked…conditions, there may be compelling public health reasons for including conditions that are not at the top of our list." There certainly are such compelling reasons to include MRSA. The spread of MRSA is so serious that

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[4] "Reducing Hospital-acquired Infections: The Business Case ," PHC4 Research Brief , Issue No. 8, November 2005, www.phc4.org.

more must be done to identify it both prior to admission and if it is acquired in a facility. In 1972, only two percent of staph infections were antibiotic resistant. By 2003, MRSA made up nearly 60 percent of all staph infections. According to the CDC, MRSA accounts for sixty to 65% of hospital-acquired staph infections.[5] Despite more than 95,000 Medicare cases with average charges of $31,088, this infection is rated near the bottom of the CMS listing, and no action is proposed because of coding problems. We understand that there are many complicating factors with regard to including MRSA, but the lack of action among hospitals to prevent the occurrence of these deadly infections is simply unacceptable, some would say criminal. This is an epidemic that fails to respond to most antibiotics available today and CMS needs to take serious action immediately. We urge that CMS convene a special work group to make hospital acquired MRSA a higher priority.

We make similar comments about other hospital-acquired infections not likely to be included in the first year of 5001(c) events:

- Surgical Site Infections (SSI): Every state reporting law includes SSIs related to selected surgeries. This is one area on which most hospitals concentrate their infection control efforts, yet it remains a significant problem. The CDC recently estimated that approximately 20 percent of hospital-acquired infections are SSIs – or 274,000 SSIs each year -- two in every 100 procedures.[6] We urge CMS to identify SSIs associated with several common procedures - for example, hip and knee replacement surgeries - and include at least some of these in the first year.

- Ventilator Associated Pneumonia (with an estimated extra cost to the health care system of $2.5 billion): We urge CMS to keep working on this and to push for improved ways to identify when nosocomial VAP occurs and for amending the current CDC definition of VAP. For too long, experts in the medical field have complained about this unworkable definition and it needs to be dealt with quickly. The results from the Institute for Healthcare Improvement's 100,000 Lives campaign clearly indicate that effective prevention practices exist. This is the deadliest of hospital-acquired infections and needs to be addressed.

- Vascular Catheter-Associated infections (with a quarter million cases per year): We appreciate that CMS is planning to create a code(s) to identify this condition and support adding it in 2009.

As the CMS analysis shows, it is relatively easy to include in the 5001(c) conditions (1) catheter-associated urinary tract infections, (2) pressure ulcers, (3) serious preventable events, (4) air embolism, and (5) blood incompatibility, and Staphylococcus aureus Bloodstream Infection/Septicemia. To act immediately on all six of these conditions will be a major step forward for patient quality—and savings for taxpayers. We support including all six of these conditions on the initial list.

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[5] "MRSA in Healthcare Settings," http://www.cdc.gov/ncidod/dhqp/ar_MRSA_spotlight_2006.html, 2006.
[6] Klevens, Monina R., p. 163.

We strongly support including catheter-associated urinary tract infections (UTI). Only one state reporting system (Pennsylvania) is requiring hospitals to track UTIs and very few hospitals focus infection control efforts on them. Including UTIs on this initial non-payment list will no doubt finally give hospitals the impetus to do something about this very common, costly, yet easily preventable, hospital-acquired infection. This item alone will have a huge impact on reducing infection rates.

We also strongly support the inclusion of Staph aureus bloodstream infections (septicemia), another high volume, high cost hospital-acquired infection, with a death rate of about 41% or 12,000 fatalities a year and an extra cost of $9.5 billion. We appreciate the discussion of the complexities of the coding problems, but with human and financial costs so high, we urge that resolving these coding problems be made a priority and that CMS list Septicemia as comprehensively as possible.

We support 5001(c) and do not believe patients and taxpayers should pay for such poor quality of care. We appreciate the agency's willingness to work through the technical coding and paperwork problems that exist in many of these situations. Ultimately, hospitals need to do a better job of identifying conditions patients bring with them when admitted to the hospital and, more important, of identifying those patients who are infected or injured while hospitalized. Public reporting laws and Medicare non-payment for the treatment of these injuries will bring about these long-needed changes. A hospital could then be rewarded (or penalized) for its bottom line infection rate and performance, and consumers could 'vote with their feet' in rewarding the higher quality institutions. We realize that this goal may take several years, but it is a journey worth starting.

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

We strongly support the expansion of the quality items that must be reported in order to receive the full payment update (i.e., not face a reduction of 2 percentage points) to include five anti-infection process measures. For calendar year 2009, we support the inclusion of three new infection prevention measures:

> --SCIP Infection 4: Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose;
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> --SCIP Infection 6: Surgery Patients with Appropriate Hair Removal;
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> --SCIP Infection 7: Colorectal Patients with Immediate Postoperative Normothermia.

In the CMS listing of additional measures that might be considered, we urge you to proceed to include additional infection prevention measures, regardless of whether they have been formally agreed to through the sometimes overly-lengthy consensus process. Specifically, we support the inclusion of urinary catheter-associated urinary tract infection (UTI) for ICU patients as an outcome measure. This is the most common hospital-acquired infection and most hospitals are unaware of the extent of the problem

within their facilities. Pennsylvania hospitals, the only state that requires tracking UTIs, identified 11,265 UTIs in 2005, with a statewide infection rate of 7.2 per 1000 cases and a mortality rate of 8.7. The length of stay for these patients was four times longer than the average patient.

Most importantly, it is time to give the public information on hospital specific HAI rates. Pennsylvania, Missouri and Florida are doing it and other states will soon follow. There is no reason for Medicare to be lagging so far behind in this life-saving and money-saving effort. The CMS notice references an effort underway by the NQF to consider the recommendation of reporting various infection rates. This must be treated with more urgency: on average, about 10 Americans per hour are dying from HAI.[7] . We cannot afford to wait for further study, as infections are growing more resistant to treatment faster than we as a nation are addressing the issue.

With respect to the CMS desire to 'retire' quality measures that are no longer relevant, Consumers Union would say that as much as it supports and appreciates the inclusion of the various infection prevention process measures, they should all eventually be replaced with a comprehensive public reporting of HAI infection rates. Reporting infection rates leaves it to hospitals to use whatever process measures and other strategies they feel appropriate to achieve a low infection outcome. Curbing HAI takes a comprehensive approach and infection rates will reveal which hospitals are taking such an approach. The notice refers to a desire to "balance the competing goals of assuring the development of a comprehensive yet parsimonious set of quality measures while reducing reporting burden on hospitals." Then, focus on outcomes. It is impractical for the CMS Hospital Compare system to keep adding process measures each year. Further, process measures do not always translate into improved outcomes.

Generally, we urge CMS to turn its focus on outcome measures relating to issues other than hospital-acquired infections. Thus, we support the other outcome measures listed for inclusion and possible inclusion, such as readmissions and AHRQ quality and patient safety indicators.

With respect to validation of data being submitted by hospitals, we understand that in FY 2008 CMS will not be applying the validation requirement to 3 SCIP anti-infection measures (Infection 2, VTE 1 and 2). Since this data comes from the hospitals and it can impact their business, it is imperative to include validation processes to assure the public that the information is accurate. We appreciate the Agency making it clear that they will be subject to validation in FY 2009 and, since they trigger Federal payments, we believe they may already be subject to the False Claims Act.

With respect to public reporting, combining data across multiple campuses hides from consumers serious quality problems at a single facility. The notice states that 5-10% of hospitals report in this manner, which could have an impact on many consumers. As long as this grouping is in place, the public must be informed as to which facilities are falling

[7] 100,000 deaths each year divided by 365 days, then by 24 hours, or 11.4 infections per hour.

into these groups. But it is ultimately more important to address the underlying problem that is preventing CMS from reporting the performance of each individual hospital. We urge CMS to report the quality measures for each specific hospital campus.

One more issue we would like to raise that is not addressed in the notice is coordination with the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN), the successor of the agency's National Nosocomial Infection Surveillance System. Many of the states passing infection reporting laws will be using the NHSN to analyze hospital data; one major state, New York, has already begun reporting through this network and eventually well over a thousand hospitals will do the same. As CMS considers reporting infection rates, it should ensure coordination with CDC to avoid duplication of efforts by hospitals that are complying with state laws, but also want to be eligible for the full market basket updates. We urge CMS to begin working on this immediately.

IMPACT STATEMENT

We seriously challenge the conclusion in the Impact Statement relating to Hospital-Acquired Conditions, including infections, found in section VII. A of the CMS document suggesting the expected savings from this proposal will be minor. While the direct savings based on non-payment may be minimal, the savings resulting from preventing HAI and other events could be significant. For example, if every hospital began systematically following CDC guidelines on urinary catheters in an attempt to prevent non-payment for patients who get a urinary tract infection (UTI), the cost savings to Medicare (as well as other payers) from preventing high volume/high cost UTIs could be quite substantial. The threat of non-payment will be a big motivator for hospitals to be more diligent in complying with CDC guidelines that have been published for many years. We believe the number of deaths from HAI and the additional costs have been well documented in a number of studies. Reducing the rate of infection will be a money saver to payers, but more importantly, it is a life saver, and therefore justifies more urgency and action in stopping HAIs.

Thank you for your consideration of these comments.

Sincerely,

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