June 11, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
C5-01-17
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore MD 21244

Re: CMS-1488-P
HSRV Weights
DRGs: Severity of Illness

Dear Dr. McClellan:

BioMedical Strategies LLC (BMS) wishes to comment on CMS-1488-P, "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates" regarding the proposed introduction of "consolidated severity-adjusted DRG" (CS-DRG) methodology as well as HSRVcc cost-based weights to the Inpatient Prospective Payment System (IPPS). BMS has experience in medical economics, statistics, coding and other issues regarding the introduction of new technology into medical practice. Our comments are based on this experience as well as our successful experience with the development of consensus standards for classification of medical procedures.

There will be many comments to the Federal Register from industry and others detailing flaws in the proposed CS-DRG and HSRVcc methodologies and potential serious negative consequences to the health care system of the US due to a flawed payment methodology. However, BMS believes that in addition to flawed methodology, the design of the proposed CS-DRG classification and weighting algorithms *fundamentally* does not meet the needs of CMS, its Medicare beneficiaries or health service providers. Furthermore, the reliance of the CS-DRG methodology on 3M's proprietary APR DRG grouping logic and software may not be in compliance with Public Law 104-113, The National Technology Transfer and Advancement Act of 1995.

3M's APR DRG classification system was designed for statistical measurement of quality of care and the utilization of services in hospitals, and not for prospective payment system needs. Furthermore, it contains arbitrary decisions and unvalidated assumptions that may affect its suitability for an IPPS. Because the 3M system is inadequate for CMS' needs, CMS has modified the APR DRG system to construct its CS-DRG system. However, CMS' process for this modification was neither transparent nor subjected to sufficient expert review and criticism before publication in the proposed rule. Furthermore, the CS-DRG weights are calculated from poor quality charge and cost data, which requires CMS to use extensive "cleaning" procedures and statistical methods that may also be subject to substantial errors.

The Federal Register notice states that CMS is interested in public comments on whether there are alternative DRG systems that could result in better recognition of severity than the CS-DRGs. Thus, BMS wishes to propose an alternative that would create a new, non-proprietary

DRG classification and weighting system that is specifically designed for IPPS payment purposes, and using procedures that are consistent with Public Law 104-113.

Public Law 104-113. states "…all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments." The consensus standards process enables creation of a new classification and weighting system by a transparent and validated process that is open to input and criticism not only from Government, but also from a full spectrum of experts (e.g., medical, statistical, economic) and stakeholders (any interested party) in hospital services and payments. In addition, many of the problems in translation of the hospital charges reported on the claims forms to the hospital costs that CMS needs for weighting, as well as its data quality problems, could also be solved at their source by applying consensus standardization to the charge accounting for claims and to cost reporting.

A voluntary consensus standards body is described by the following attributes:

(i) Openness.

(ii) Balance of interest.

(iii) Due process.

(iv) An appeals process.

(v) Consensus, which is defined as general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons why, and the consensus body members are given an opportunity to change their votes after reviewing the comments.

A proven consensus standards body that has experience in medical technology and medical procedure classification is ASTM International. BMS recommends that CMS participate in the formation of expert committees within the ASTM International to develop a standardized DRG classification and severity adjustment system for the IPPS. ASTM International has a long-standing history of providing support to virtually all government agencies through their balanced, neutral and open forum, providing complete standards services in the form of staff support, customized e-media support, publishing and distribution management, and industry outreach to bring stakeholders to the program. By using this consensus standards process, CMS' objectives could be realized at little cost to the Government, and with superior accuracy and fairness to both beneficiaries and providers.

By participating in developing a standard, CMS would not be obligated to use it, nor would it be precluded from modifying it to address its policy or other concerns. But, in addition to meeting its obligations under OMB Circular A-119 and the National Technology Transfer and Advancement Act (Public Law 104-113), the consensus standards process has many advantages to CMS:

(i) It eliminates much of the cost to CMS of developing its own standards and decreases the cost of software procured and the burden of complying with agency regulation.
(ii) It provides incentives and opportunities to establish a DRG system of higher quality that will further national needs.
(iii) It encourages long-term growth for U.S. healthcare institutions and commercial enterprises and promotes efficiency and economic competition through harmonization of standards.
(iv) It furthers the policy of reliance upon the private sector to supply Government needs for goods and services.

While the specific content of the new classification and weighting system would be determined by the consensus process under our proposal, BMS suggests that there are issues in addition those identified by the MedPAC that the consensus process could address, such as these:

(i) DRG severity levels are based on primarily on clinical and demographic patient characteristics. While clinical coherence is an important feature of a DRG system, insufficient attention has been given to alternatives to discrete DRG classes for severity adjustment. Severity adjustment by a linear statistical model based on the effect of secondary diagnoses and procedures on costs or charges may be superior to these discrete classes, and would have the advantage of avoiding the creation of groups with low incidence.
(ii) Both the existing and proposed DRG classification and weighting systems do not sufficiently consider best practice guidelines or the consequences of treatment options on post-discharge morbidity, quality of life, or the prognosis for further treatment post discharge. In the cases when superior treatments increase hospital costs, there is a powerful financial disincentive to the hospital, with multiple consequences: beneficiaries may be denied the most effective care, the overall costs to Medicare may be increased, and there is a barrier to the introduction of better technology.
(iii) The introduction of ICD-10-CM will result in yet another disruption to the payment system. BMS recommends that that a new IPPS system be based on the ICD-10-CM, both for better accuracy and to avoid another disruptive system transition. A mapping of ICD-10-CM to and from ICD-9-CM could address interim hospital needs or those of other payers.

BioMedical Strategies LLC has substantial experience with ASTM International standards for medical classifications. We would be pleased to assist CMS in developing and implementing a consensus standardization process.

Very truly yours,

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