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July 5, 2011

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Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-3213-P: Proposed Rule: "Medicare and Medicaid Programs; Influenza Vaccination Standard for Certain Participating Providers and Suppliers" (42 CFR Parts 482, 485, 491, and 494)

Dear Dr. Berwick,

As an association representing behavioral healthcare provider organizations and professionals, the National Association of Psychiatric Health Systems (NAPHS) appreciates the opportunity to respond to the proposed rule (CMS-3213-P) titled "Medicare and Medicaid Programs; Influenza Vaccination Standard for Certain Participating Providers and Suppliers" as published in the May 4, 2011, *Federal Register*. We are happy to provide our suggestions – particularly related to behavioral health organizations that provide services to those who are experiencing mental and addictive disorders.

ABOUT NAPHS

Founded in 1933, NAPHS advocates for behavioral health and represents provider systems that are committed to the delivery of responsive, accountable, and clinically effective prevention, treatment, and care for children, adolescents, adults, and older adults with mental and substance use disorders. Our members are behavioral healthcare provider organizations, including more than 700 psychiatric hospitals, addiction treatment facilities, general hospital psychiatric and addiction treatment units, residential treatment centers, youth services organizations, outpatient networks, and other providers of care. Our members deliver all levels of care, including inpatient treatment, residential treatment, partial hospitalization, and outpatient services.

As behavioral healthcare providers, we care for millions of individuals with serious and persistent mental illnesses and serious addictive disorders, many of whom are enrolled in either the Medicare or Medicaid programs – or both.

COMMENTS

Conditions of Participation Are Not the Right Approach

We agree that the widespread immunization of the population against influenza results in significant public health benefits. However, we are very concerned about the precedence set by making immunization a responsibility of hospitals by virtue of incorporating it into the Medicare conditions of participation (CoPs). Historically, the responsibility for immunization against communicable diseases has rested with the primary care and public health systems. Rates of influenza immunization have risen substantially over time through the use of these systems. Hospitals have taken significant responsibility in supporting these efforts through their various outpatient and primary care functions. When an individual need has been identified, hospitals have delivered influenza vaccine to inpatients. The current proposed rule creates punitive enforcement processes targeted against hospitals. CoPs articulate structures and processes that providers must develop in order to ensure provision of their contractual responsibilities to Medicare beneficiaries. The CoPs do not list specific actions or processes (such as administration of specific medications) that must be performed. This proposed rule is a serious departure from the reasons for COPs, and it creates a bad precedent.

Reimbursement Issues Are Unclear

It is unclear how hospitals paid under the inpatient psychiatric facility (IPF) prospective payment system (PPS) would be reimbursed for influenza immunizations. Under the IPF PPS, all medications are included in the daily rate (with the exception of pneumococcal vaccine). Should this proposed rule be adopted, reimbursement needs to be clarified. The rule could potentially require psychiatric hospitals to immunize all patients who had previously not been immunized at any point in time. Based on NAPHS *Annual Survey* data, this could be as many as 2,247 patients in a typical 50- to 100-bed psychiatric hospital within the NAPHS membership (or up to 4,014 patients in a typical hospital with more than 100 beds).

Use of Scarce Resources Has Not Been Thought Through

Distribution mechanisms for influenza vaccine do not necessarily follow the normal medication procurement mechanism. Agencies order the vaccines in advance based on historical need. If this requirement were implemented, hospitals (and specifically psychiatric hospitals) would have no idea how much vaccine would be required since it is impossible to predict how many patients would need it. Vaccine may be inappropriately stockpiled (and subsequently wasted), resulting in inefficient distribution of limited vaccine at potentially great cost.

Timeline Is Not Feasible

The aggressive timeline for implementation of the proposed rule makes it impossible for hospitals (and particularly psychiatric hospitals) to obtain vaccine by September 2011. Most agencies have already ordered the vaccine by now. We think the amount of time allocated to the administrative implementation of the proposed policies and procedures as well as the burden of patient education of risks and benefits, obtaining consent, and administration and documentation of the vaccine is woefully underestimated in the proposed rule.

Potential for Overimmunization Exists

The chance of overimmunization (that is, patients receiving vaccine more than once) clearly exists when patients are receiving vaccinations from two systems (inpatient and outpatient) that do not necessarily communicate with each other. In its zeal to be compliance with the

COPs, it would be understandable that a hospital would be inclined to immunize patients who could not provide proof of prior immunization and were willing to consent to immunization.

RECOMMENDATIONS

In summary, NAPHS recommends that:

- The proposed rule **not** be implemented as part of the CoPs. Inclusion of these requirements is a substantial and inappropriate departure from the intention of the CoPs.
- *If* implemented, the timeframe for implementation should be adjusted – put back at least one year – to allow hospitals time to prepare.
- Reimbursement policies be clarified.
- Supply chain questions be reexamined.

CONCLUSION

We look forward to continuing to work with CMS and the Department of Health and Human Services to ensure high quality services for Medicare and Medicaid beneficiaries.

Sincerely,

Mark Covall
President/CEO