Re: Consumer Comments regarding proposal from the Centers of Medicare and Medicaid Services to reduce government survey visits to hospitals by replacing them with self-reporting mechanism

Donald M. Berwick, MD, MPP
Administrator
Centers for Medicare & Medicaid Services,
7500 Security Boulevard
Baltimore, MD 21244

Nov 10, 2010

Dear Dr. Berwick,

This is a comment regarding the proposal from the Centers of Medicare and Medicaid Services (CMS) by Thomas Hamilton, Director of the Survey and Certification Group, CMS, to reduce government survey visits to hospitals by replacing them with self-reporting through the fulfillment of the hospital's QAPI requirements. The following statements were made, which have given us concern, during a teleconference entitled, "Accelerating Healthcare-Associated Healthcare-Infection Elimination: Health System, Hospital, and Government Leadership Collaboration," on Oct. 28, 2010.

> "And the question that arises with regard to survey and certification is, why do we need so many surveys? How could we arrange things so that external surveys would be less and less necessary? I think part of the solution to that is to try to strengthen the internal capability of every type of organization to monitor its own performance and act on that information."
>
> "Over the course of the next two years, what we intend to do is to develop further the attention that we are focusing on the hospital's QAPI requirements, so that hopefully we could look more at those functionalities within a hospital and reduce the need for surveyors to be looking at the other areas, so that we can have the confidence going into an organization that if there are problems, that organization is mindful of the problems and is taking prompt and effective action. "

The above proposed protocol appears to use self-reporting and self-policing for quality assurance and oversight. However, protocols based on self-reporting and policing have come into question as to their effectiveness by healthcare stakeholders.(1) The following is documentation of the shortcomings of protocols based on self-reporting.

> The December 2008 OIG report by Levinson (OEI-06-07-0047) outlined problems with self-reporting and self-policing in facilities, including the reporting of only an estimated 0.1% of sentinel events to the Joint Commission. (1)
>
> A March 2010 Joint Commission report stated that only 4,590 reports of sentinel events from general hospitals and 298 reports of sentinel events from emergency rooms had been received since January 1995.(63) Only 64.7% of these reports were identified by self-reporting.(2)
>
> A March 8, 2010 OIG Report found that in surveyed hospitals, patient diagnosis codes were

inaccurate or absent for 7 of the 11 Medicare Hospital Acquired Conditions identified by physician reviewers and reviewed hospitals did not generate incident reports for 93% of the 120 events. Two out of the three events which caused death did not have any reports.(3)

A recent AHRQ survey (Sorras AHRQ March 2009) found 52% of the staff in 622 surveyed facilities did not report any adverse events (sentinel or otherwise) at their institution. The report concluded that, "It is likely events were underreported," and identified this as an area for improvement. (4)

The AMA News reported that as of 2007, approximately half of U.S. hospitals had never reported a physician to the National Practitioner Data Bank. (5)

In Kentucky, a glaring example of possible non-reporting exists, where in a submitted 2010 grant to the CDC for control of Healthcare Acquired Infections (6) clearly states that HAI outbreaks are reportable to the State Health Departments but a survey of the total reports revealed that over a year's time, in 100 acute care facilities, only four reports were made.(7) No outbreaks of C. Diff or MRSA were reported in hospitals.(7) In addition, these reports did not differentiate between hospital acquired and pre-existing infections.

Based upon the above evidence we strongly urge the Centers of Medicare and Medicaid not to curtail survey visits which are vitally needed to verify submitted data and to assure the quality of care provided to patients.

Thank you for this consideration,

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Donald Wright, MD, MPH -- Deputy Assistant Secretary for Healthcare Quality, Office of the Secretary, US Dept HHS

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Sheila Roman, MD, MPH – Senior Medical Officer, Hospital and Ambulatory Policy Group, CMS

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Marc Hartstein – Deputy Director, Hospital and Ambulatory Policy Group, CMS

References:

(1) Levinson DR. Adverse Events in Hospital: Overview of key issues. Dept. of Health and Human Services, Office of Inspector General. Dec 2008, Page 25
http://oig.hhs.gov/oei/reports/oei-06-07-00470.pdf

(2) Sentinel Event Statistics. The Joint Commission. March 31, 2010.
http://www.jointcommission.org/NR/rdonlyres/377FF7E7-F565-4D61-9FD2-593CA688135B/0/SE_Stats_9_09.pdf

(3) Levinson DR. Adverse Events in Hospitals. Methods for Identifying Events. March 2010. Office of Inspector General. Dept. of Health and Human Services. OEI 06 08 00221, Page 15
http://oig.hhs.gov/oei/reports/oei-06-08-00221.pdf

(4) Sorras J. Famolaro T, Dyer N, Nelson D, and Khanna K. Hospital Survey on Patient Safety Culture: 2009 Comparative Database Report . AHRQ Pub No 09-0030. March 2009, Page 4.
http://www.ahrq.gov/qual/hospsurvey09/

(5) Sorrel AL. When is conduct reportable? National Practitioner Data Bank takes complaints from hospitals about physicians. American Medical News Sept 21, 2009
http://www.ama-assn.org/amednews/2009/09/21/prsa0921.htm

(6) Kentucky State and Regional Infection Prevention and Epidemiology Program (K-STRIPE) Healthcare Associated Infections Prevention Plan . State Plans to Address Healthcare-Associated Infections. Posted May 27, 2010. http://www.cdc.gov/HAI/pdfs/stateplans/ky.pdf

(7) Humbaugh, KE. In a letter from the Cabinet for Health and Family Services, Department for Pubic Health, Division of Epidemiology and Health Planning. Nov. 1 2010 (see enclosure)

CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH
Division of Epidemiology and Health Planning

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Janie Miller
Secretary

November 1, 2010

Kevin T. Kavanagh, MD
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Dear Dr. Kavanagh:

In response to your request, dated and received on October 21, 2010, for "aggregate data on healthcare acquired infection and multidrug resistant outbreaks" reported by healthcare facilities, the Kentucky Department for Public Health is able to supply the following information.

During the period from October 1, 2009 to September 30, 2010, fifty-one total outbreaks were reported in healthcare facilities in Kentucky. Of these, four were reported by hospitals (in two, the cause was confirmed as norovirus; in one, it was confirmed as a multidrug resistant organism, and in one, the causative agent remained unconfirmed). Forty-six outbreaks, all associated with gastrointestinal symptoms, were reported by nursing homes or long-term care facilities (in twenty, the cause was confirmed as norovirus; in one, it was confirmed to be *C. difficile;* and in twenty-five the causative agent remained unconfirmed). Finally, one outbreak was reported in another type of healthcare facility, and the cause of this outbreak was not determined.

Because in most instances outbreaks are the result of a mixture of affected staff and patients, we do not distinguish between those which may be primarily the result of introduction of an organism into a facility and those mainly due to transmission within a facility.

If you have any questions, please contact me at (502)564-3418 ext 3570.

Sincerely,

Kraig E. Humbaugh, M.D., M.P.H.
Director, Division of Epidemiology and Health Planning

cc: Dr. William Hacker
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