Round Table on Hospital Reporting to The National Practitioner Data Bank -- October 29, 1996

Summary of Presentation by Sidney M. Wolfe, M.D. Director, Public Citizen's Health Research Group

1. Issues Involved in Reporting:

The fundamental question underlying the OIG report is whether the level of reporting by hospitals to the NPDB is "too low," and represents underreporting of adverse actions and/or failure of hospitals to take reportable adverse actions. In our January 1995 comments on the OIG report, we called the level of reporting by hospitals "suspiciously low," and still believe this to be the case. Indeed, the evidence indicates that there is substantial underreporting, and as the first step to addressing the variety of issues raised by hospital reporting, we should acknowledge that current reporting levels are too low – even if we disagree as to the causes or solutions.

According to the OIG report, as of December 31, 1993, about 75 percent of all hospitals in the United States had never reported an adverse action to the Data Bank. The updated data (through August 31, 1996) indicate that hospital reporting has *decreased* since the OIG report. The strongest indication that there is underreporting is based on comparing the level of negligence in hospitals as estimated by studies such as the Harvard Medical Practice Study, with the number of adverse actions reported by hospitals to the Data Bank. The 1991 Harvard Medical Practice Study found that one percent of hospitalizations in New York state in one year involved adverse events caused by negligence, including almost 7,000 deaths. This result, projected to hospitals nationwide, suggests that 80,000 patients a year are killed by negligence in hospital settings alone. At this rate, there would have been 480,000 patient deaths due to negligence in hospitals over the six-year period (9/90 - 8/96) in which hospitals reported only 4,968 adverse actions to the Data Bank. While there is no reason to expect an exact match between these measures, the magnitude of the difference strongly suggests that there is inadequate reporting.

Another indication that there is underreporting is the variation in reporting found from state to state. There is no reason to believe that the occurrence of adverse events varies greatly from state to state, yet the OIG report found that the reporting rate ranged from 8.5 adverse actions per 1,000 hospital beds in Nevada to 0.7 per 1,000 beds in South Dakota.

2. Barriers to Reporting:

There has been the suggestion that a major barrier to reporting is inadequate immunity for physicians participating in peer review. The paper prepared by Victoria Smith of Northwestern University reviews the cases dealing with the immunity provisions of the Health Care Quality Improvement Act of 1986, and concludes that

the fears physicians have regarding the protections of the HCQIA are unfounded, and that the level of immunity provided by the Act provides adequate protection for peer review activities. The paper does not address the question of whether there is a chilling effect on peer review caused by physicians' *erroneous* belief that immunity is inadequate, and this may be a subject for further study or educational efforts.

3. Possible Solutions:

The first step towards a solution is to better understand the magnitude and causes of the problem. One question is whether the number of hospital reports is low because the hospitals are taking actions but failing to report them, or whether the hospitals are not taking reportable actions (for example, by increasing 29-day privileging actions). A comparison should be made of the number of adverse actions reported by hospitals to state medical boards under state reporting laws, with the number reported to the NPDB. Large differences in any state should prompt closer investigation (although this would not capture cases where there is also underreporting to state boards).

Another approach would be for the OIG to take a random sample of reported licensure actions to determine whether there was or should have been an adverse action taken or reported by a hospital. In addition, intensive cases studies of the extent and nature of adverse actions in particular hospitals, as suggested in the OIG report should be conducted.

The second step towards a solution is to create better detection and enforcement methods. Current regulations provide that if the Secretary of HHS has reason to believe that a hospital has substantially failed to report information as required by the law, the Secretary will conduct an investigation. If ultimately there is a finding of noncompliance, the sanction provided is for the hospital to lose the immunity provided by the Act for a 3-year period. [45 CFR Part 60.9] This process is inadequate, and formal mechanisms to detect non-reporting are needed. (Such a mechanism, for example, might include automatic review of any reported malpractice payments where the event took place in a hospital to see if an adverse event should have been initiated or reported.)

Finally, the current sanction for failure to report – the loss of immunity for a period of three years – is insufficient. The HCQIA authorizes monetary penalties up to $10,000 per incident for failing to report payments on malpractice claims, as well as for violations of the confidentiality provision. Legislation should be proposed to authorize monetary penalties up to $10,000 per incident for hospitals that fail to report to the Data Bank as mandated by law. This would make hospital penalties at least comparable to those applied to malpractice insurers who fail to submit payment reports.