REPORT OF THE
JOINT COMMISSION ON HEALTH CARE

Patient Safety and Medical Errors Study

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

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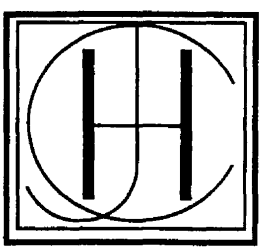


Preface

House Joint Resolution 9 of the 2000 General Assembly Session (Appendix A), as introduced, directs the Joint Commission on Health Care (JCHC) to study the 1999 report of the Committee on Quality Health Care in America, and to examine the efficacy and appropriateness of implementing its recommendations in the Commonwealth. This resolution was not adopted by the General Assembly but was communicated via letter from the Speaker of the House of Delegates to the JCHC. The Speaker's letter, which is included in Appendix A, states:

> "The House Rules Committee believes that the issues addressed by the resolution merit review. Therefore the Commission is directed to undertake the study and submit a written report of its findings and recommendations to the Governor and the 2001 Session of the General Assembly."

HJR 9 specifies that, in conducting the study, JCHC is to examine current Virginia and national data regarding adverse medical events; review current patient safety initiatives in Virginia health care practices; and develop specific recommendations for the implementation of patient safety measures in Virginia.

Based on our research and analysis during this review, we concluded the following:

- A report issued by the Institute of Medicine (IOM) in 1999 concluded that "medical errors" are a serious health problem, and estimated that as many as 44,000 to 98,000 Americans die each year as a result of preventable adverse events. The IOM concluded that medical errors occur primarily due to systemic, as opposed to individual, failures within the health care delivery system.

- The IOM issued nine recommendations to address issues surrounding medical errors. Some of the recommendations involve roles and functions typically performed by states. The IOM recommendations included: (1) reporting of information concerning serious adverse events to states; (2) implementation of meaningful patient safety programs with defined executive responsibility; (3) purchaser-developed incentives for health care organizations to demonstrate continuous improvement to patient safety; and (4) periodic re-examination and re-licensing of health care professionals.

- In response to the IOM report, health care organizations in Virginia have formed a coalition called Virginians Improving Patient Care and Safety (VIPCS). One of the goals of VIPCS is the development of better systems to support health professionals and to ensure safe practices.

- Several national organizations, including the National Patient Safety Foundation established by the American Medical Association, are also seeking to promote patient safety and advocate best practices.

- The Joint Commission on Accreditation of Health Care Organizations (JCAHO) monitors "sentinel events," which are unexpected occurrences involving death or serious physical or psychological injury, or the risk thereof. Health care organizations are encouraged, but not required, to voluntarily report sentinel events to JCAHO. Since 1995, JCAHO has received approximately 800 reports of sentinel events for the entire United States. The number of these that have been voluntarily reported has been rather low, due to liability concerns on the part of health care providers.

- Purchasers of health care services, particularly large purchasers, are a potential source of significant influence to promote patient safety throughout the health care delivery system. However, only 34 percent of respondents to a JCHC staff survey of hospitals agree that health plans have established expectations for patient safety improvements on the part of providers.

- Patient safety issues are addressed, at least indirectly, through various state and federal regulatory activities, including Medicare requirements and investigation of sentinel events by the Virginia Department of Health.

- The Department of Health Professions (DHP) is now using medical malpractice payment information as a basis for commencing standard of care investigations. DHP is also making progress towards implementing an Internet-based physician profiling system which will contain a variety of information including final disciplinary actions and medical malpractice awards and settlements.

- Hospital incident reporting systems are intended to identify events that represent a variance from established policies and procedures (e.g., a patient fall, medication error, etc.). Virtually all hospitals that responded to a JCHC survey report that their systems are administered in a non-punitive manner in support of quality assurance efforts. However, many survey respondents also cited factors believed to serve as barriers to the internal reporting of incidents, such as an institutional "culture of blame" and concerns about malpractice litigation.

- Hospital risk management and quality assurance information is generally protected from discovery in litigation. However, some health care providers cite the need for statutory protections from legal discovery to be specifically extended to any type of external reporting system for adverse events.

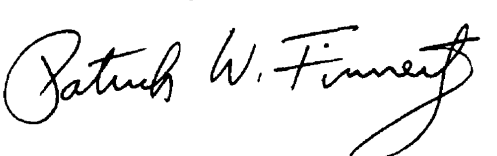
- Virginia's patient level database, maintained by Virginia Health Information (VHI), contains certain data that are related to patient safety. These data (known as "e-codes") pertain to surgical and medical "misadventures," adverse drug effects, and surgical and medical procedures that are the cause of an abnormal reaction. These data indicate a very small, but increasing, percentage of inpatient hospital discharges for which such events were reported. Forty-six percent of the JCHC survey respondents agreed that such data have potential value for evaluating adverse medical events in Virginia.

- The federal and state governments are continuing to search for ways to effectively and responsibly address the broad range of issues identified in the IOM report. At the federal level, a national agenda for patient safety research is being developed. At the state level, efforts are continuing to evaluate the various types of adverse event reporting systems that are in operation. In Virginia, VIPCS is continuing to work on patient safety issues, and is developing a patient safety brochure for distribution to consumers.

A number of policy options were offered for consideration by the Joint Commission on Health Care regarding the issues discussed in this report. These policy options are listed on pages 55-57.

Public comments were solicited on the draft report. A summary of the public comments is attached as Appendix B.

On behalf of the Joint Commission on Health Care and its staff, I would like to thank each of the member organizations of VIPCS, as well as the Virginia Department of Health Professions , the University of Virginia, the Medical College of Virginia, and the Virginia Trial Lawyers Association for their cooperation and assistance during this study.



Patrick W. Finnerty
Executive Director

December 2000

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I.
Authority for the Study

House Joint Resolution 9 of the 2000 General Assembly Session (Appendix A), as introduced, directs the Joint Commission on Health Care (JCHC) to study the 1999 report of the Committee on Quality Health Care in America, and to examine the efficacy and appropriateness of implementing its recommendations in the Commonwealth. This resolution was not adopted by the General Assembly but was communicated via letter from the Speaker of the House of Delegates to the JCHC. The Speaker's letter, which is included in Appendix A, states:

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Report Outline

This report presents the results of JCHC's staff review as directed by HJR 9 and is divided into six sections. This section discussed the authority for the study. The second section provides a general overview of the 1999 Report of the Committee on Quality Health Care in America, and discusses the reaction of the federal government to the report. The third section reviews various patient safety initiatives currently underway within the health care delivery system. The fourth section discusses statutory and regulatory requirements that are pertinent to patient safety in Virginia. The fifth section reviews public policy approaches that other states have taken with respect to patient safety. The sixth and final section presents policy options.

II.
Overview of the 1999 Report of the Committee on Quality Health Care in America

The Quality of Health Care in America Project Was Initiated by the Institute of Medicine in 1998 With the Charge of Developing a Strategy That Will Result in a Threshold Improvement in Quality Over the Next Ten Years

The Quality of Health Care in America Committee was formed by the Institute of Medicine. The Institute of Medicine (IOM) is chartered by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. The IOM serves as an adviser to the federal government, and can act on its own initiative in identifying issues of medical care, research, and education.

The purpose of the IOM Quality of Health Care in America Committee is to:

- review and synthesize findings in the literature pertaining to the quality of care provided in the health care system;
- develop a communications strategy for raising the awareness of the general public and key stakeholders of quality of care concerns and opportunities for improvement;
- articulate a policy framework that will provide positive incentives to improve quality and foster accountability;
- identify characteristics and factors that enable or encourage providers, health care organizations, health plans, and communities to continuously improve the quality of care; and
- develop a research agenda in areas of continued uncertainty.

The Committee's initial report, "To Err is Human: Building a Safer Health Care System," (commonly referred to as the "IOM Report") focused on various types of errors and preventable adverse events that occur within the health care system, and means by which they can be prevented. Many types of errors can occur within the health care delivery system. These include:

- diagnostic (i.e. error or delay in diagnosis, or failure to employ indicated tests);
- treatment (i.e. error in the performance of an operation, procedure or test, or error in the dose or method of using a drug);
- preventive (i.e. inadequate monitoring or follow-up of treatment);
- equipment failure; and
- communication failure.

The IOM report is the first of a planned series of reports on quality-related issues by the IOM. Future reports are planned for areas such as redesigning the health care delivery system, aligning financial incentives to reward quality care, and the role of information technology as a tool for measuring quality.

The IOM Report Concluded That Medical Errors Are a Serious Problem

The IOM reported highlighted in detail a longstanding problem in that sometimes patients are harmed rather than helped by the medical care they receive. According to the IOM report, health care is not as safe as it should be. Clearly, not all medical errors result in actual harm to patients. However, the report presented evidence, drawn from more than 40 published studies, indicating that various types of medical errors, including medication errors, are a leading cause of injury and death.

The two leading studies cited by IOM focused on hospitals in the states of New York, Colorado, and Utah. The New York study, also known as the Harvard Medical Practice study, was published in 1991 and examined more than 30,000 randomly selected discharges from 51 randomly selected hospitals in New York State in 1984. The key findings of that study included:

- adverse events occurred in 3.7 percent of in-patient hospitalizations;
- 13.6 percent of adverse events resulted in death;
- 58 percent of the adverse events were preventable; and
- 27 percent of the adverse events were due to negligence.

According to the IOM report, the findings of the 1991 New York study have been corroborated by a 2000 study, which focused on hospitals in Utah and Colorado. That study, which examined 15,000 randomly

selected discharges from 1992 from a representative sample of hospitals, found that:

- adverse events occurred in 2.9 percent of in-patient hospitalizations;
- 8.8 percent of adverse events resulted in death;
- 53 percent of the adverse events were preventable; and
- 29 percent of the adverse events were due to negligence.

The IOM report defined a number of key terms. An "error" is defined as "the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning)." An "adverse event" is defined as "an injury caused by medical management rather than the underlying condition of the patient." An adverse event attributable to error is a "preventable adverse event". "Negligent adverse events" are a subset of preventable adverse events that "satisfy legal criteria used in determining negligence (i.e. whether the care provided failed to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question.)" Finally, safety is defined as "freedom from accidental injury."

The IOM report estimated, based on extrapolations from the state-specific studies of hospital in-patients conducted in New York, Utah, and Colorado, that as many as 44,000 to 98,000 Americans die each year as a result of medical errors. Medication errors are believed to be the single most prevalent type of medical error. The IOM also estimated, based on extrapolation, that total national costs (i.e. lost income, lost household production, disability and health care costs) due to adverse events are between $17 and $29 billion for preventable adverse events. While the percentage of adverse events found in the New York, Colorado, and Utah study appears small in absolute terms, the IOM report concludes that even that percentage is unacceptably high. The IOM report calls for a 50 percent reduction in medical errors over the next five years.

The IOM Report Further Concluded That Medical Errors Occur Primarily Due to Systemic, as Opposed to Individual or Personal, Failures

The health care delivery system is large and complex. Many different practitioners and providers, using a variety of different types of technology, can come in contact with a single patient across a wide range of care settings. According to the IOM report, "When large systems fail, it

is due to multiple faults that occur together in an unanticipated interaction, creating a chain of events in which the faults grow and evolve. Their accumulation results in an accident." However, because they usually affect just one patient at a time, accidents in health care are often not highly visible or particularly dramatic.

Obviously, the human element is a vital component of the health care delivery system. Humans will always make errors. Nevertheless, the IOM report states that health care delivery systems can and must be designed to prevent, detect and handle many different types of human errors that can be reasonably anticipated to occur. Furthermore, different types of errors are likely to require different types of solutions.

The IOM report distinguished between active errors and latent errors. Active errors occur at the level of the front line practitioner and their effects are felt almost immediately (i.e. administration of the wrong drug, or surgery on the wrong body part). Latent errors, by contrast, tend to be removed from the direct control of the practitioner. Latent errors can include things such as "poor design, incorrect installation, faulty maintenance, bad management decisions, and poorly structured organizations." According to the IOM report, current responses to errors within the health care industry "tend to focus on the active errors by punishing individuals (i.e. firing or suing them), retraining or other responses aimed at preventing recurrence of the active error." However, latent errors "pose the greatest threat to safety in a complex system because they are often unrecognized and have the capacity to result in multiple types of active errors." The IOM report concludes that focusing on the sources of latent errors is a more effective means of improving safety within health care.

The IOM Report Recommends A Comprehensive Approach to Improving Patient Safety

In several respects, the IOM report offers a relatively harsh assessment of safety practices within the health care delivery system. For example, the report states that "silence surrounds this issue", refers to a "cycle of inaction," and claims that "most third-party payment systems provide little incentive for a health care organization to improve safety, nor do they recognize and reward safety or quality." According to the IOM report, a comprehensive health care systems approach to improving patient safety is needed. The recommendations contained in the report lay out a four-tiered approach:

- establishing a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety;

- identifying and learning from errors through immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients;

- raising standards and expectations for safety through the actions of oversight organizations, group purchasers, and professional groups; and

- creating safety systems inside health care organizations through the implementation of safety practices at the delivery level.

The IOM report contains a total of nine specific recommendations, which are found in Appendix B. None of the recommendations are directed exclusively at state governments or at the types of health care functions performed by state governments. However, three of the recommendations address, in part, health care functions and roles that fall within the purview of the state. For example, one recommendation calls for the establishment of a nationwide mandatory reporting system that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. According to this recommendation:

- Reporting should initially be required of hospitals and eventually should be required of other institutional and ambulatory care delivery settings.

- The United States Congress should designate the Forum for Health Care Quality Measurement and Reporting to promulgate and maintain reporting standards, and that funds and technical expertise should be provided to state governments to establish or adapt their current error reporting systems to collect the standardized information, analyze it, and conduct follow-up action as needed with health care organizations.

- Should a state choose not to implement a mandatory reporting system, the Department of Health and Human Services should be designated as the responsible entity.

- Congress should designate a Center for Patient Safety to convene states to share information and expertise, and receive and analyze aggregate reports from the states to identify persistent safety issues.

Other IOM report recommendations with potential applicability to the state include those that call for performance standards and expectations for health care organizations to focus greater attention on patient safety. For example:

- regulators and accreditors should require health care organizations to implement meaningful patient safety programs with defined executive responsibility;

- public and private purchasers should provide incentives to health care organizations to demonstrate continuous improvement to patient safety; and

- health professional licensing bodies should (1) implement periodic re-examinations and re-licensing of doctors, nurses, and other key providers, based on both knowledge and competence of safety practices; and (2) work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action.

Reaction to the IOM Report Within The Health Care Industry Appears To Be Fairly Positive, But There Has Been Some Skepticism Concerning the Report

Among the representatives of various health care organizations in Virginia interviewed by JCHC staff, the IOM report appears to be viewed as having raised significant issues that need to be addressed in a forthright, responsible manner. However, there appears to be considerable concern as to how several of the recommendations might be implemented in practice. However, according to JCHC's staff survey of hospitals, less than half of the respondents (48 percent) agreed with the statement "The Institute of Medicine report presents an accurate portrayal of the extent of medical errors and adverse medical events." Forty percent of respondents disagreed with that statement, while twelve percent had not opinion. The JCHC survey is discussed in greater detail in Section III.

There does appear to be some skepticism, even criticism, concerning the IOM report, including:

- the national estimate of patient deaths is based on a methodologically-suspect extrapolation of relatively old data, which may have resulted in an over estimation of the extent of the problem;

- there are no practicing physicians or other practicing health care practitioners who served on the Quality of Health Care in America Committee, and is therefore somewhat lacking in "real world" perspective; and

- the study focused only on in-patient hospital settings while not examining outpatient or physician office settings, and therefore probably underestimates the extent of the problem.

The Federal Government's Quality Interagency Coordination Task Force (QuIC) Has Endorsed the IOM Recommendations and Has Developed a Strategy to Reduce Medical Errors

In December 1999, President Clinton directed the QuIC to evaluate the IOM recommendations and to respond with a strategy to identify prevalent threats to patient safety and reduce medical errors. In February 2000, the QuIC reported that it endorsed the IOM recommendations and discussed a series of actions that will be taken by federal executive branch agencies. For example:

- The Department of Defense will implement a mandatory error reporting system in its hospitals and clinics, using a model similar to that currently used by the Department of Veterans Affairs.

- The National Forum for Health Care Quality Measurement and Reporting (the Quality Forum) will identify a set of patient safety measurements critical to the identification of medical errors. This will be done within the context of a broader effort to standardize hospital performance measures. The Quality Forum is a broad based, widely representative private body charged with establishing standard quality measurement tools to help all purchasers, providers and consumers of health care better ensure the delivery of quality services. The Quality Forum has noted that the nation's hospitals currently use a wide variety of measurement systems and performance indicators to assess their quality of care.

- HCFA will develop a pilot project, through its Peer Review Organization program, for up to 100 hospitals that volunteer to implement penalty free, confidential, mandatory reporting systems.

- HCFA will promulgate regulations requiring all hospitals participating in the Medicare program to have ongoing medical error reduction programs.

- The Office of Personnel Management will require all health plans participating in the Federal Employee Health Benefits Program to implement patient safety programs.

- The Department of Labor will work with private sector employers and employees to incorporate patient safety into health care purchasing decisions.

- The Food and Drug Administration will develop new standards to help prevent medication errors caused by proprietary drug names that sound similar or packaging that looks similar, and will develop new standards for drug labels.

In addition, the President's proposed budget for FY 2001 includes $30 million to support a Center for Patient Safety within the Agency for Health Care Research and Quality.

III.
Patient Safety Activities Within The Health Care Industry

A Variety of Health Care Organizations in Virginia Have Formed a Coalition to Address Patient Safety Issues

Virginians Improving Patient Care and Safety (VIPCS) was established early in 2000 shortly after the release of the IOM report. The goals of this coalition include:

- increased awareness in professional and public circles of the need for further improvement in patient care and patient safety;
- better systems to support health professionals and ensure safe practices whenever and wherever care is delivered; and
- a more informed public, healthcare professional, and public policy decision-maker on issues of patient safety.

Members of VIPCS include the Virginia Hospital and Healthcare Association, the Medical Society of Virginia, the Virginia Association of Health Plans, the Virginia Pharmacists Association, the Virginia Nurses Association, as well as several other organizations including Virginia Health Information, Inc., private health systems, risk management associations, law firms, and durable medical equipment vendors, and one consumer representative. The Virginia Department of Health has two representatives, including the State Health Commissioner, on VIPCS.

The National Patient Safety Foundation (NPSF) Has Been Established by the American Medical Association In Order to Measurably Improve Patient Safety Within the Health Care Delivery System

The NPSF was established in 1997 by the AMA, CNA HealthPro, 3M, and Schering-Plough. The NPSF Board of Directors includes representatives from a large number of organizations, including the American Hospital Association, the American Society of Health System Pharmacists, and AARP.

In 1997, the NPSF commissioned a national public opinion survey on patient safety issues in the health care environment. Key findings of the survey, based on the responses of 1,513 adults, include:

- 42 percent of respondents have been involved, either personally or through a friend or relative, in a situation where a medical mistake was made. 33 percent of respondents reported that they had personally experienced a medical mistake.

- 48 percent of all reported mistakes occurred within a hospital, while 22 percent occurred within a doctor's office.

- 32 percent of respondents indicated that the medical mistake had a permanent negative effect on the patient's health.

- In 38 percent of all situations involving a medical error, respondents reported that nothing was done as a result of the error. By contrast, 14 percent reported that their medication was changed or corrected, 12 percent had to undergo surgery or additional tests or procedures, 10 percent changed their doctor or hospital, nine percent of respondents reported that the mistake corrected itself, and six percent reported filing a lawsuit. Only one percent reported that the health care professional involved with the mistake lost or was suspended from his job.

The NPSF, in collaboration with the Joint Commission on Accreditation of Health Care Organizations, recently announced the joint Patient Safety 2000 initiative. This is aimed at encouraging the submission of successfully tested and implemented methods, products and strategies to the two groups to reduce medical errors. The joint initiative seeks to identify practical solutions across many areas, including processes to ensure safe error reporting, improving systems and risk management, and maximizing the use of new technology.

There Are Several Additional National Organizations That Seek To Promote Patient Safety Through Educational Activities and Dissemination of Information Concerning Best Practices

There is no shortage of readily available information concerning best practices for the prevention and reduction of medical errors and adverse medical events. Numerous national organizations have published information intended to help promote safety improvements within the health care delivery system. These include the Institute for Health Care Improvement, the Institute for Safe Medication Practices, the Health Care Advisory Board, and the United States Pharmacopeia.

The Institute for Health Care Improvement (IHI) has advocated adoption of several "high leverage changes" in order to reduce the incidence of errors. These changes include, but are not limited to:

- creating clear guidelines and standards for writing medication orders;

- standardizing the number of dosing options; and

- developing pre-printed order forms with detailed listing of dose limits for chemotherapy drugs.

The Institute for Safe Medication Practices (ISMP) receives voluntarily-reported information concerning medication errors from a variety of sources and, upon analysis of the data, publishes medication safety alerts for practitioners, consumers, regulatory bodies and industry. According to ISMP, some common sources of medication error in health systems include:

- critical information concerning the patient not being available prior to dispensing or administering drugs;
- failure of unit-dose systems to thoroughly prepare, package and label medications, and a lack of adequate checking and screening by pharmacy and nursing personnel;
- stocking multiple concentrations of the same drug, or storing drugs in look alike containers or in ways that obscure drug labels;
- lack of standardization in drug delivery devices, improper equipment default settings and unsafe equipment (i.e. free-flow infusion pumps);
- limited staff education and patient education concerning error prone situations; and
- environmental stress (i.e. noise, excessive interruptions) that can affect individual performance.

ISMP has developed a Medication Safety Self-Assessment instrument, which has been provided to all hospitals in the United States. This tool provides characteristics of a safe hospital medication system, and allows hospitals to identify possible opportunities for improvement within its medication delivery process.

The United States Pharmacopeia (USP) develops standards for drug products and disseminates information about the use of medicines. In 1995, USP was instrumental in establishment of the National Coordinating Council for Medication Error Reporting and Prevention. The purpose of this independent body, comprised of 19 national health care organizations, is to address the interdisciplinary causes of errors and to promote the safe use of medications.

USP operates two separate voluntary medication error reporting programs. The oldest of the two is the Medication Errors Reporting Program (MERP) which is operated in cooperation with ISMP. Under the MERP, practitioners who encounter actual or potential medication errors can report confidentially to USP. Each report is reviewed by USP for health hazards, with all information subsequently forwarded to the FDA, ISMP, and the product manufacturer. Practitioners must provide identifying information to USP, but can also direct USP not to release their personal information to any external party. USP uses the reported information as a basis for developing and providing medication safety information to practitioners, industry, and the general public.

USP has recently developed an additional reporting mechanism and database called MedMARx. The MedMARx system enables a hospital to track and analyze errors that occur in its own facility, and to compare its facility with other hospitals, on a de-identified basis, across the country. The system provides standard definitions of medication errors, and contains an index for categorizing medication errors. For a fee, which ranges from $2,000 to $4,000 based on the size of a hospital, a hospital can purchase access to this Internet-based system. MedMARx contains various error categories which range in severity. Based on data reported to the system during 1999, the most common category of error is one in which an error occurred that reached the patient but that did not cause the patient harm. Figure 1 summarizes errors reported to MedMARx by error category.

MedMARx is still relatively new, having been introduced in August 1998. Since then, approximately 200 hospitals have purchased access to the system. In Virginia, 23 percent of respondents to the JCHC hospital survey reported that they currently utilize MedMARx.

The Health Care Advisory Board conducts research which focuses on health system strategies, revenues, cost, governance, and operations. The Clinical Initiatives Center within the Advisory Board Company focuses on the introduction and implementation of new and best-demonstrated practices for improving clinical quality and reducing clinical cost. In 1999, the Clinical Initiatives Center published "Prescription for Change: Best Practices in Medication Management."

The American Hospital Association (AHA) and the Medical Group Management Association (MGMA) have formed a partnership to improve patient safety. The AHA and MGMA will develop joint communications on medication safety practices that work, examine tools for assessing pharmacy safety in ambulatory settings, and provide education and training to help clinicians and managers implement safer practices.

Figure 1

Medication Errors Reported to the USP MedMARx System During 1999

Error Category	Number of Cases
There Was No Actual Error but the Reported Circumstances or Events Have the Capacity to Cause Error	498
An Error Occurred but There Was No Harm to the Patient	5,549
An Error Occurred Which Resulted in Harm to the Patient	176
An Error Occurred Which Resulted in the Patient's Death	1

Source: JCHC Staff Analysis of USP MedMARx data.

The Joint Commission on Accreditation of Health Care Organizations (JCAHO) Focuses On Prevention of Sentinel Events

JCAHO is a national accrediting organization for hospitals and several other types of health care organizations, such as ambulatory care and home care. JCAHO accreditation is a voluntary process conducted for the purpose of promoting performance improvement. Hospitals that are accredited by JCAHO are deemed by HCFA to be certified to participate in the Medicare and Medicaid programs. JCAHO certification is provided for a three-year period following satisfactory completion of a JCAHO survey. Nationally, about 80 percent of all hospitals and 95 percent of all hospital beds, are accredited by JCAHO. Within Virginia, the percentage of JCAHO accredited hospitals is well above the national average, with 93 of the 98 licensed hospitals (95 percent) being JCAHO-accredited.

Health care organizations must adequately perform various specified functions, in compliance with JCAHO standards for each function, in order to receive JCAHO accreditation. One of the required

functions is "Improving Organization Performance." The goal of this function is to ensure that the organization has well-designed processes and systematically monitors, analyzes and improves its performance to improve patient outcomes. In the course of seeking to improve organization performance and patient outcomes, JCAHO expects health care organizations to focus on reducing "sentinel events". JCAHO defines a sentinel event as:

> An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof (i.e. any process variation for which a recurrence would carry a significant chance of serious adverse outcome). Serious injury specifically includes loss of limb or function. The following items are also considered sentinel events, even if the outcome was not death or a major permanent loss of function: suicide of a patient in a setting where the patient receives around-the-clock care, infant abduction or discharge to the wrong family, rape, hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities, or surgery on the wrong patient or wrong body part.

JCAHO requires that any time a sentinel event occurs, the accredited health care organization is expected to complete a thorough and credible root cause analysis, implement improvements to reduce risk, and monitor the effectiveness of those improvements. The root cause analysis is expected to dig down to underlying organization systems and processes that can be altered to reduce the likelihood of human failure in the future and to protect patients from harm when human error does occur.

Under JCAHO's sentinel event policy, sentinel events are subject to review by JCAHO and may be reported to JCAHO by health care organizations on a voluntary basis. Alternatively, JCAHO may become aware of a sentinel event by some other means such as through a patient, family member, employee of the organization, or through the media. If JCAHO becomes aware, either through voluntary self-reporting or otherwise, of a sentinel event, the health care organization is required to prepare and submit to JCAHO a root cause analysis and action plan. Upon receipt, JCAHO evaluates the organization's response to the sentinel event.

JCAHO originally wanted the reporting of sentinel events to be mandatory, but health care organizations expressed opposition to this based on concerns of legal liability. Essentially, health care organizations feared that the reporting of this type of information to an external entity

such as JCAHO would waive existing legal confidentiality protections and as a result would make the information subject to legal discovery in medical malpractice litigation. In response, JCAHO made the reporting policy voluntary. JCAHO does state that it will not disclose legally protected sentinel event information to any other party and will vigorously defend the legal confidentiality of this information in court.

JCAHO believes that health care organizations derive several advantages from voluntarily reporting sentinel events to JCAHO, including that:

- reporting the event enables the addition of the lessons learned from the event to be added to JCAHO's sentinel event database, thereby contributing to the general knowledge about sentinel events and the reduction of risk for such events in other organizations; and

- the organization's message to the public that it is doing everything possible to ensure that such an event will not happen again is strengthened by its acknowledged collaboration with JCAHO to understand how the event happened and what can be done to reduce the risk of such an event occurring in the future.

Based on the results of its analysis of the sentinel events, JCAHO publishes and distributes a newsletter titled "Sentinel Event Alert" in order to share information concerning the occurrence, management and prevention of sentinel events.

Since the reporting system was first implemented in 1995, the number of sentinel events reviewed by JCAHO, as well as the number of sentinel events self-reported by health care organizations, has increased rapidly:

- JCAHO reviewed 333 sentinel events in 1999, compared to only 23 in 1995.

- The percentage of sentinel events that were voluntarily self-reported was 83 percent in 1999, compared to only 4 percent in 1995.

Figure 2 summarizes the ten most prevalent types of sentinel events in the JCAHO database. JCAHO reports that 79 percent of the sentinel events it has reviewed have resulted in the death of the patient.

Respondents to JCHC's Survey of Hospitals Report a Wide Variety of Approaches to Addressing the Identification and Prevention of Medical Errors

JCHC staff surveyed the 98 acute care general hospitals licensed in the state. The purpose of the survey was to collect data concerning existing quality of care and patient safety systems and processes, and current regulatory requirements. The survey was also designed to provide hospital staff with an opportunity to express their viewpoints concerning a variety of issues related to the study. Survey responses were received from 44 hospitals, for a 45 percent survey response rate.

Figure 2

Most Prevalent Types of Sentinel Events Reviewed by JCAHO

Type of Sentinel Event	Number of Occurrences	Percent of All Sentinel Events
Patient Suicide	169	19.4
Medication Error	118	13.6
Operative/Post-Operative Complication	100	11.5
Wrong Site Surgery	72	8.3
Delay in Treatment	42	4.8
Patient Fall	39	4.5
Assault/Rape/Homicide	37	4.3
Patient Death/Injury in Restraints	36	4.1
Patient Elopement	31	3.6
Transfusion Error	22	2.5
All Other Types of Sentinel Events	204	23.4

Source: Joint Commission on Accreditation of Health Care Organizations.

The JCHC survey of hospitals requested respondents to identify the different types of practices used within their institutions to identify and prevent the occurrence of adverse drug events. The items in the survey were drawn from best practices for medication management, published by the Clinical Initiatives Center of the Advisory Board Company in 1999.

The recommended best practices for identification of adverse drug events are as follows:

- inspection points – hospital tracks data collected from discrete points within the medication process;
- focus groups – meetings of key personnel in the medication process to obtain input on key sources of errors and to identify potential solutions;
- monitoring error markers – monitor critical laboratory results and antidote medications that suggest an adverse drug event has occurred;
- chart review – detailed review of a sample of medical records coupled with case investigation to determine the incidence and probable cause of adverse drug events; and
- observation – the hospital deploys trained personnel to observe and record a random sample of medication administration errors.

A majority of the respondents reported that the first three of these recommended practices have been fully implemented in at least some area of the hospital, and frequently throughout the entire hospital (Figure 3). The use of chart reviews was less fully implemented among respondents. Observation was the least used recommended best practice among the survey respondents. Nearly half of the respondents, and all of the respondents with less than 100 beds, reported no activity in this regard.

The Clinical Initiatives Center has also published recommended best practices for preventing the occurrence of adverse drug events. These include practices intended to support ordering of medications by physicians, utilize the expertise of pharmacists, promote the accurate writing of medication orders, better ensure the precise dispensing of medications, and reinforce and supplement the hospital's nursing staff. Figure 4 summarizes the reported level of activity among the JCHC survey respondents in terms of each of these recommended best practices.

Figure 3
Activities Performed by Virginia Hospitals to Identify the Occurrence of Adverse Drug Events
(Percent of Respondents Indicating a Level of Activity for Each Practice)

	No Activity	Discussed but Not Implemented	Partially Implemented in Some Areas	Fully Implemented in Some Areas	Fully Implemented Throughout Entire Hospital	Unknown/ Not Sure
Inspection Points	9%	9%	11%	18%	48%	5%
Focus Groups	2%	11%	23%	20%	43%	0
Monitoring Error Markers	14%	9%	16%	16%	43%	2%
Chart Review	18%	9%	20%	9%	39%	5%
Observation	48%	11%	9%	7%	20%	5%

Note: 44 of 98 hospitals (45 percent) responded to the survey. Percentages do not all total 100 due to rounding.
Source: JCHC staff analysis of data collected from JCHC survey of licensed acute care hospitals.

Among the recommended best practices listed in Figure 4, a majority of respondents reported that they have fully implemented the following in least some areas of their hospital:

- pharmacist intervention database,
- pre-printed order forms, and
- pharmacist order entry.

In contrast, a majority of respondents reported no activity concerning the use of bar code reconciliation technology or dedicated medication personnel. With regard to several of the other recommended practices (i.e. diagnosis-specific standing orders, pharmacy-managed protocols, and automated dispensing systems) there is a considerable amount of reported variation among the respondents.

Figure 4
Activities Performed by Virginia Hospitals to Prevent the Occurrence of Adverse Drug Events
(Percent of Respondents Indicating a Level of Activity for Each Practice)

	No Activity	Discussed but Not Implemented	Partially Implemented in Some Areas	Fully Implemented in Some Areas	Fully Implemented Throughout Entire Hospital	Unknown/ Not Sure
Prescribing Medications – Supporting Physician Ordering						
Pharmacist Intervention Database	5%	12%	16%	7%	58%	2%
Pocket Formulary	42%	19%	2%	5%	19%	9%
Prescribing Medications – Supporting Physician Ordering						
Diagnosis-specific standing orders	2%	12%	40%	23%	23%	0
Computerized Physician Order Entry	43%	49%	7%	0	0	2%
Prescribing Medications – Leveraging Pharmacy Expertise						
Pharmacist Interview of Patient	35%	14%	35%	7%	5%	5%
Pharmacy Managed Protocols	16%	16%	28%	16%	30%	2%
High Risk Rounding List	42%	14%	14%	19%	7%	5%
Dedicated Unit Pharmacist	44%	14%	9%	16%	14%	2%
Order Processing – Writing Orders Accurately						
Zero-tolerance ordering standards	30%	18%	11%	7%	16%	18%
Pre-printed order forms	5%	5%	34%	27%	27%	2%
Pharmacist Order entry	21%	5%	2%	12%	53%	7%
Order Processing – Dispensing Drugs Precisely						
HAZMAT dispensing protocols for chemotherapy orders	18%	5%	18%	8%	35%	18%

Figure 4 (continued)

Activities Performed to Prevent the Occurrence of Adverse Drug Events (Percent of Respondents Indicating a Level of Activity for Each Practice)

	No Activity	Discussed but Not Implemented	Partially Implemented in Some Areas	Fully Implemented in Some Areas	Fully Implemented Throughout Entire Hospital	Unknown/ Not Sure
Order Processing – Dispensing Drugs Precisely						
Automated dispensing systems	23%	16%	16%	21%	23%	2%
Drug Delivery – Reinforcing and Supplementing Nursing Staff						
Dosing crib sheets	28%	7%	28%	19%	5%	14%
Bar code reconciliation	75%	20%	0	0	0	5%
Dedicated medication personnel	61%	11%	5%	7%	11%	5%

Note: 44 of 98 hospitals (45 percent) responded to the survey. Percentages do not all total 100 due to rounding.
Source: JCHC staff analysis of data collected from JCHC survey of licensed acute care hospitals.

The JCHC survey also requested hospitals to assess their level of activity in relation to risk reduction strategies, published by JCAHO in February 2000 as part of its Sentinel Event Alert series, pertaining to the prevention of operative and post-operative complications. Figure 5 summarizes the reported level of activity among the JCHC survey respondents. A majority of the respondents reported full implementation, in at least some areas of the hospital, of improved staff orientation and training and standardized procedures across care settings. In several other areas, such as revising credentialling and privileging, revising the competency evaluation process, and monitoring the consistency of compliance with procedures, there was considerable variation among respondents.

Figure 5

Activities Performed by Virginia Hospitals to Help Minimize the Occurrence of Operative and Post-Operative Complications (Percent of Respondents Indicating a Level of Activity for Each Practice)

	No Activity	Discussed but Not Implemented	Partially Implemented in Some Areas	Fully Implemented in Some Areas	Fully Implemented Throughout Entire Hospital	Unknown/ Not Sure
Improving staff orientation and training	5%	7%	31%	17%	36%	4%
Educating and counseling physicians	12%	17%	36%	12%	17%	7%
Expanding on-call coverage	34%	22%	9%	2%	17%	17%
Standardizing procedures across settings of care	2%	5%	21%	38%	26%	7%
Revising credentialing and privileging	27%	15%	10%	12%	27%	10%
Clearly defining expected channels of communication	14%	12%	29%	10%	33%	2%
Revising the competency evaluation process	5%	19%	33%	10%	24%	10%
Monitoring consistency of compliance with procedures	5%	17%	31%	14%	29%	5%

Note: 44 of 98 hospitals (45 percent) responded to the survey. Percentages do not all total 100 due to rounding.

Source: JCHC staff analysis of data collected from JCHC survey of licensed acute care hospitals.

Virginia's Schools of Medicine, Nursing, and Pharmacy State That They Incorporate Patient Safety Issues Into Their Curriculums

Instruction and training regarding patient safety and error prevention can be characterized as having both informal and formal components. At Eastern Virginia Medical School (EVMS), the informal or anecdotal approaches include all of the interactions of experienced

clinicians with their students. This can include the clinician recounting a story of a patient's case that went awry, a post-hoc analysis of the cause of the problem; and a caution on what steps to take to prevent such a recurrence. EVMS also reports formal curricular approaches in at least four areas: (1) efforts to foster a culture in which medical mistakes are admitted, discussed, and dealt with; (2) educational presentations of systematic approaches to quality assurance/improvement; and (3) reducing risk to patients by identifying common causes of error and addressing them prospectively (i.e. illegible handwriting).

At the Medical College of Virginia (MCV) School of Medicine, during each year of medical school, students are involved in formal and informal small groups to discuss issues of safety, care, and precision in discussing error rates. Even in the first two non-clinical years, the "Foundations in Clinical Medicine" and the pharmacy course include some of these elements. In addition, the clinical departments review death and other complicated cases in formal teaching conferences.

The University of Virginia (UVA) school of medicine explains that the care of patients and the education of medical students and residents are inseparable. A new in-service education program focused on the tools and philosophy of continuous quality improvement and root cause analysis methodologies has been developed for the entire hospital and clinic operation. Medical students and residents learn about patient safety measures by caring for patients within this improved system. In terms of specific coursework, the "practice of medicine" course discusses cases that emphasize patient safety and the prevention of errors.

The MCV School of Nursing, through the first clinical course of its undergraduate program, addresses procedures designed to assure patient safety in the administration of medication. The graduate program includes a specific course in pharmacology and pharmacy in which medication and prescription error prevention is a course objective.

The UVA School of Nursing reports that the topics of patient safety, and medical error prevention and reduction, are core to undergraduate nursing education leading to a B.S.N. degree. Undergraduates are instructed concerning codes of conduct and principles of accountability. In terms of medication administration, students are expected to know a drug's purpose and rationale for each patient, adverse effects, monitoring requirements, and drug/drug interactions. In the M.S.N. program, clinical rounds pay special attention to the importance of having knowledge of the patient's current condition as well as possible previous reactions to medications or other complicating conditions. Collaboration with clinical preceptors involve specific conversations about safety issues. Several

courses in the M.S.N. program prepare the student to deal effectively with ethical dilemmas in practice. According to UVA, "having experienced advance practice nurses involved in direct patient care is perhaps the most effective way of reducing medical errors throughout the institution."

The MCV School of Pharmacy requires first-year students to participate in the "Understanding and Preventing Medication Errors Program" developed by USP in conjunction with ISMP. During the second year, students participate in "Errors and Omissions" exercises, in which they check prescriptions and drug orders that have been filled by a pharmacy technician. The students also begin "Rx Review" exercises during the second year. In this, they check prescriptions and patient medication files to detect inappropriate prescribing. During the fourth year, students are placed in clerkship rotations to obtain advanced professional practice experiences. In each rotation, medication error prevention is addressed in several ways, including:

- medication history taking and monitoring drug therapy in acute care (i.e. at the patient's bedside) pharmacy settings; and

- interpretation of medication orders and dispensing of medications in hospital or community pharmacy settings.

The Shenandoah University School of Pharmacy stated that one of the challenges inherent in the education and training of new pharmacists is the proliferation, within the pharmacy profession, of information systems used for drug tracking. For example, each chain drug store has its own proprietary drug tracking system. In addition to making it more difficult for practicing pharmacists to monitor their patients (who may receive medications from many different pharmacies), this situation also makes it more difficult to educate students as to the types of data that they will be expected to collect, access, and analyze upon graduation. Shenandoah University also stated that there is a need to establish an incentive-based reimbursement system for pharmacists in order to provide a higher level of payment for certain "high-risk" drugs. The purpose of such a system would be to support improved monitoring by pharmacists of patients using these drugs.

Purchasers of Health Care Services Are a Strong Potential Source of Leverage to Promote Patient Safety Within the Health Care Delivery System

Large group purchasers of health care services, and the health insurance plans and/or managed care organizations with which they typically contract, are uniquely positioned to positively influence the

implementation of effective patient safety and medical error reduction efforts by health care providers. Nationally, many large corporations, including General Motors, General Electric, and GTE, are beginning to focus on the use of specifically-designed purchasing strategies to reward "high-value" health care services, in which value is explicitly defined to include safe patient care. In so doing, such large purchasers have proposed requiring that health care providers with whom they do business implement certain specified "best practices" within a given period of time. These include computerized physician order entry systems for improved medication management, and the use of evidence-based hospital referral including the use of mortality rates.

Many large purchasers require that health plans with which they contract be accredited by the National Committee for Quality Assurance (NCQA). In order to receive accreditation, a health plan must comply with NCQA accreditation standards, and compare satisfactorily to other plans on selected performance measures in NCQA's Health Plan Employer Data and Information Set (HEDIS). In evaluating a health plan, NCQA evaluates many plan characteristics including:

- evidence that the health plan has looked for information on any malpractice suits or sanctions;
- a well-defined program for continuously improving the quality of clinical care and service provided to plan members;
- individuals in the health plan responsible for overseeing quality improvement efforts;
- actual improvements that the plan has made in care and service;
- evidence that health plans' decisions about medical treatment and service are based on acceptable standards for medical practice;
- distribution of guidelines that assist doctors with providing the right care to plan members with acute conditions;
- evidence of monitoring the quality of care provided to plan members with specific acute conditions; and
- evidence that the health plan is working to improve the quality of care provided to plan members with specific acute conditions and correcting any problems of poor quality.

Based on review by JCHC staff, it does not appear that NCQA accreditation standards and the HEDIS data elements explicitly focus on the types of patient safety and medical error prevention issues raised in the IOM report. However, these issues may be addressed indirectly through the NCQA standards. According to a representative of the Virginia Association of Health Plans, the NCQA is very interested in the IOM report and is examining how to address patient safety issues. Individual

health insurance plans may, independent of NCQA, review and analyze data pertaining to patient safety issues. However, only thirty-four percent of the respondents to the JCHC hospital survey agreed with the statement: "Health insurance plans have established expectations for improvements in patient safety on the part of health care providers." Fifty-seven percent of respondents disagreed with that statement and nine percent had no opinion.

Michigan is an example of a state that has been active in seeking to use the purchasing power of the state to promote improved patient safety practices. The Michigan Department of Community Health, which administers the state's Medicaid program, has collaborated with private purchasers in several areas, including trying to reduce administrative burdens on health care providers by collaborating on evaluation efforts. Michigan advocates that various state health programs (i.e. Medicaid, state employee health benefits, SCHIP, mental health, and corrections) form a coalition to focus on the issue of patient safety in all purchasing decisions, including the development of incentive payment mechanisms to reward high quality of care.

In Virginia's Medicaid program, the Department of Medical Assistance Services (DMAS) is required to comply with HCFA requirements for conducting external quality review. States have a certain amount of flexibility in how to perform this function. A few years ago, DMAS performed a two-year study of medical errors within its Medallion II managed care program. During the study, physicians and nurses reviewed medical records following the death of Medallion II enrollees to determine if the death was attributable to medical errors. DMAS officials report that, based on this review, none of the deaths were found to be attributable to medical errors.

The contract established by DMAS to provide managed care services for the Medallion II program requires contracting health plans to have an internal quality improvement program. This must include:

- internal quality studies,
- coordination and continuity of care,
- coordination of quality improvement activity with other management activity,
- utilization management,
- credentialling and recredentialling policies, and

- monitoring and evaluation of enrollee complaints.

The Virginia Department of Human Resource Management (DHRM), which administers the State and Local Employee Health Benefits Program, has historically issued Requests for Proposals for insurance coverage that contain a number of specific quality assurance criteria. According to DHRM staff, however, that was not the case during the past year. In an effort to obtain as many proposals from health insurance carriers as possible, the normal type of quality assurance screening criteria were not utilized.

IV.
Virginia's Statutory and Regulatory Environment

Medicare Conditions of Participation Address Quality Assurance and Are a Major Source of Regulation for Providers

Federal regulations promulgated by HCFA establish more than 20 Medicare "conditions of participation" for hospitals. These include quality assurance, infection control, medical staff, nursing services, pharmaceutical services, and many others. According to the quality assurance condition of participation, "the governing body must ensure that there is an effective, hospital-wide quality assurance program to evaluate the provision of patient care". This must include evaluation of nosocomial infections and medication therapy, as well as evaluation of the appropriateness of diagnosis and treatment of all medical and surgical services. The hospital is required to take and document appropriate remedial action to address deficiencies found through the quality assurance program.

Among the respondents to the JCHC hospital survey, 65 percent of the respondents agreed with the statement: "Requirements and regulations of the Medicare program provide an adequate incentive for hospitals to aggressively pursue issues concerning patient safety. The United States Health Care Financing Administration (HCFA) is in the processing of developing revised Medicare (and Medicaid) conditions of participation for hospitals. The proposed revisions place added emphasis on performance improvement.

State Hospital Regulations for Hospitals Include Several Provisions Related to Quality Assurance and Patient Safety

Section 32.1-127 of the *Code of Virginia* requires "minimum standards" for the construction and maintenance of hospitals, nursing homes, and certified nursing facilities "to assure the environmental protection and the life safety of its patients and employees and the public." Contained within Virginia's hospital regulations are some specific provisions that appear generally related to the concepts of promoting quality assurance and patient safety. These include requirements for:

- mechanisms for the review of medical care;
- periodic review and revision of patient care policies and procedures;
- a quality control program designed to ensure the reliability of laboratory data;

- an infection control committee responsible for establishing infection surveillance and control policies and programs;
- reporting any outbreak of infectious disease, including nosocomial infections;
- a monitoring program to identify adverse drug reactions;
- an organized anesthesia department/service (for those hospitals providing surgery or obstetrical services), the policies of which are required to address the safety of the patient during the anesthesia period; and
- a reliable method of identifying each patient, including newborn infants.

Virginia Department of Health (VDH) staff make an effort to monitor sentinel events, as defined by JCAHO, that occur in hospitals. VDH may learn of some sentinel events as the result of a complaint. VDH has also learned of sentinel events through media reports, or in some instances the event has been voluntarily self-reported. According to VDH, from 1997 through 1999, it received information concerning 24 sentinel events in Virginia hospitals (Figure 6). Most of these were not self-reported by hospitals.

VDH inspects hospitals (as well as nursing homes, home health agencies, and hospice facilities) every two years in order to ensure compliance with state regulations. VDH also performs on-site inspections in response to complaints. During its on-site inspections, VDH staff report that they pay attention to the types of quality assurance systems that the hospital has in place. For example, VDH is interested in the types of issues that the hospital identifies as problems, and actions that are taken in response. According to VDH staff, most Virginia hospitals have pretty good quality assurance systems in place, at least in terms of written policies. Among the respondents to the JCHC survey, 66 percent agreed with the statement: "The hospital licensure process administered by the Virginia Department of Health provides an adequate level of attention to issues concerning patient safety." Thirty percent of respondents disagreed, and four percent had no opinion.

In the mid-1990's, VDH attempted to examine records generated through hospital peer review processes as another source of information to monitor hospital quality assurance systems. However, §32.1-25 of the *Code of Virginia* was amended in 1998, repealing the authority of VDH to examine hospital peer review materials as part of on-site inspections. However, according to VDH staff, these records can still be obtained if an inspection is conducted pursuant to federal Medicare regulations.

Figure 6
Sentinel Events Occurring in Virginia Hospitals
(1997 – 1999)

Event Description	Regulatory Violations Found?	Self-Reported?
7 fires	2 involved regulatory violations	5 were self reported
1 Obstetrical death	No	No
Unsterile instruments used for surgery	Yes	No
Patients shot at each other in emergency department	No	No
Nurse administered intentional narcotic overdose	Yes	No
2 blood transfusion errors	Yes	Yes
HIV + blood fraction administered	No	No
1 suicide by hanging	Yes	No
1 suicide by jumping off hospital roof	No	No
1 fall from hospital roof	Yes	No
2 deaths on psychiatric unit of a general hospital with missing resuscitation equipment	Yes	No
1 death due to restraint use	Yes	No
1 occurrence in which babies were switched at birth	Yes	No
1 surgery on the wrong leg in an ambulatory surgery center	Yes	No

Source: Virginia Department of Health.

The current state hospital regulations were adopted in May 1982. The regulations were amended once in 1993 and three times in 1995. According to VDH staff, Virginia's hospital regulations are fairly old, particularly in comparison with current nursing facility regulations. VDH is considering a process and timetable for review of the hospital regulations (as well as the home health agency and hospice regulations), but a date to begin the review has not yet been established.

The Inspector General of the U.S. Department of Health and Human Services (HHS) Has Criticized The System of External Review of Hospital Quality Across the United States

In a series of reports issued in 1999, the Office of the Inspector General (OIG) within HHS concluded that the system of external quality oversight for hospitals – consisting of JCAHO, HCFA, and state survey and certification agencies - has significant strengths that help protect patients but also has major deficiencies. According to the OIG report, JCAHO surveys provide an important vehicle for reducing risk and fostering improvement. In addition, state agency investigations offer a timely, accountable means for responding to complaints and adverse events. However, the OIG also concluded that JCAHO surveys are unlikely to detect substandard patterns of care or individual practitioners with substandard skills. The OIG also reported that the system of external hospital review, led by JCAHO, is moving toward a collegial mode of oversight and away from a regulatory mode. On the other hand, state survey and certification agencies are rooted in a more regulatory approach to oversight. But HCFA, through the proposed Medicare conditions of participation, is looking for the state agencies to follow JCAHO's lead. The OIG concluded that the emerging dominance of the collegial mode may undermine the existing system of patient protection afforded by accreditation and certification practices, and contrasts significantly with the current regulatory emphasis in nursing home oversight.

In response to the report, JCAHO refuted many of the OIG's conclusions. JCAHO stated that it was not aware of any evidence that a strict regulatory approach has had any lasting effects in improving patient safety or quality of care. JCAHO also stated that over 85 percent of accredited hospitals are cited for deficiencies in their systems or processes, and are closely monitored over time until the substandard patterns of performance are remedied. The American Hospital Association stated that the primary function of accreditation is to reduce risk by ensuring that certain structures and processes are present and functioning as intended – as opposed to assessing the appropriateness of care and identifying poor performing practitioners.

JCAHO is making certain changes to its standards and practices. For example, it is drafting additional patient safety standards. It has also begun to make unannounced visits to health care organizations.

The Virginia Department of Health Professions (DHP), and the Various Health Regulatory Boards, Have Begun to Address Several Recommendations from a Series of JLARC Studies in 1998 and 1999

The Joint Legislative Audit and Review Commission (JLARC) issued reports in 1998 and 1999 that were highly critical of DHP's disciplinary and enforcement process. JLARC issued a total of 42 recommendations. According to DHP management, it has begun to address several of the recommendations that were directed to the agency. For example:

- the Board of Health Professions (BHP) is now taking a more active role in the oversight of the disciplinary process;
- BHP is conducting periodic reviews of the regulations of the various health regulatory boards to determine whether the regulations protect the health, safety, and welfare of the public;
- a full-time executive director for BHP has been hired;
- additional investigative staff will be hired in FY 2001;
- recommendations for the development of formal time guidelines for (1) the resolution of most disciplinary cases within one year, and (2) expeditious handling of serious misconduct allegations, are being prepared;
- the backlog of past-due pharmacy inspections is expected to be resolved by June 30, 2000;
- all pharmacies will now receive a routine inspection every two years; and
- information concerning medical malpractice payments is now being used as a basis for commencing standard-of-care investigations.

According to DHP management, most of the JLARC recommendations that were directed to the General Assembly, calling for consideration of amendments to the *Code of Virginia*, have not been addressed. Such recommendations include those to:

- ensure that no more than one-third of the members of any health regulatory board serve concurrent terms;

- provide for greater private citizen representation on various health regulatory boards;

- prohibit any individual who has had his or her licensed revoked from a health regulatory board from reapplying for a substantial period of time;

- make the process for license or certificate reinstatement uniform for all health regulatory boards;

- require that all licensees report unprofessional, incompetent, or substandard conduct of care by any other practitioner licensed by the same board;

- authorize DHP to access the National Crime Information Center to conduct criminal background checks on candidates for licensure; and

- change the gross negligence standard used in disciplinary cases by the Board of Medicine, and define the negligent practice of medicine as a violation of law.

The *Code of Virginia* Specifies Types of Information That Must be Reported to DHP By Health Care Practitioners and Organizations

The *Code of Virginia* establishes a series of mandatory reporting requirements to DHP on the part of numerous entities, including hospitals and other health care institutions, professional associations, and health maintenance organizations (HMOs). These statutory requirements are summarized in Figure 7. According to statistics maintained by DHP, it received 2,512 case reports from July 1, 1999 through March 30,2000. Consumers were the largest source of cases received for review (724 reports or 29 percent), followed by reports considered "Required/Mandatory" (568 reports or 23 percent). Other licensees accounted for 145 reports, or 6 percent. By contrast, professional associations (7 reports or 0.3 percent) and employers (15 reports or 0.6 percent) were relatively minimal sources of information for the DHP investigatory process. According to DHP management, it is of the opinion that the rate of compliance with its mandatory reporting requirements is rather low.

Figure 7

Mandatory Reports to Be Submitted to the Department of Health Professions

Code of Virginia Section	Entity Required to Report	Information to be Reported
54.1-2906	Chief administrative officer and chief of staff of every hospital or health care institution; and State Health Commissioner	(1) Information indicating a licensed professional may be guilty of unethical, fraudulent, or unprofessional conduct; (2) Any disciplinary action taken or begun by the institution as a result of conduct involving professional ethics, professional incompetence, moral turpitude, or substance abuse; (3) Voluntary resignation from the staff or voluntary restriction or expiration of privileges while under investigation or during disciplinary proceedings.
54.1-2908	Medical Society of Virginia, Osteopathic Medical Association, Virginia Chiropractors Association, Inc., Virginia Podiatric Medical Association, and the Virginia Physical Therapy Association	Any disciplinary action taken by the organization against any member of the organization, if such disciplinary action is the result of conduct involving professional ethics, professional incompetence, moral turpitude, drug addiction, or alcohol abuse.
54.1-2909	Any person licensed by the Board of Medicine; All licensed health care institutions; Any HMO licensed by Virginia	Any evidence that indicates a reasonable probability that a person licensed by the Board of Medicine is or may be professionally incompetent, guilty of unprofessional conduct or mentally or physically unable to engage safely in the practice of his profession.

Source: JCHC staff analysis of Code of Virginia, and JCHC staff interviews with DHP management.

This is attributed to ignorance of these statutory requirements and also reluctance to report on the part of hospital administrators.

There Are Competing Philosophies Concerning How to Best Ensure the Continued Competency of Health Care Practitioners

During interviews with JCHC staff, the initial reaction of DHP management to the IOM report recommendation for periodic re-examination and re-licensure of health care professionals, based on both knowledge and competence of safety practices, was to note that this would represent a radical change. One member of DHP management explained that there are two competing philosophies behind this issue. One view, as evidenced by the IOM recommendation, calls for all providers to undergo a recredentialing process. The other philosophy, which appears to be dominant across the country at this time, attempts to focus on problem providers through a disciplinary process. According to DHP management, no states currently require re-examination as a condition of licensure, although a few states do require a periodic "assessment." Consequently, it was stated that an entire new battery of licensing examinations would need to be developed, which would be an expensive and time consuming process. It was also noted that a professional license is considered a "property right", and, therefore, to take away a license DHP is legally obligated to provide due process to the affected professional.

Several members of DHP management suggested that, rather than focusing on re-examination, greater attention could perhaps be paid to continuing education as a means of promoting improved patient safety. Currently, the Board of Medicine and the Board of Pharmacy require continuing education as a condition of licensure, but the Board of Nursing does not. Pharmacists are required to complete at least 15 hours of continuing education during the year immediately preceding the license renewal date. According to the American Council on Pharmaceutical Education, 15 hours per year is the most prevalent requirement across the country.

Physicians are required to complete 60 hours of continuing education every two years. Board of Medicine regulations state that activities or courses shall be chosen by the physician to address such areas as "ethics, standards of care, patient safety, new medical technology, and patient communication." Assuming 30 hours of continuing education per year, Virginia's continuing education requirements for physicians appear to be well within the norm of what most other states require. Annual continuing education requirements in other states range from a low of 12

hours (Alabama) to a high of 50 hours (Massachusetts, Michigan, Ohio, and Washington).

In terms of continuing education requirements for nursing licensure, Virginia is one of the least restrictive states in the nation. According to the National Council of State Boards of Nursing, 32 of the 50 states have some type of continuing education requirement. Among the 18 states that currently do not require continuing education, 13 (including Maryland and North Carolina) do require periodic refresher courses. However, the refresher courses required by Maryland and North Carolina are only for those persons whose licenses have lapsed for five years or more and who now wish to return to work. According to representatives of the Virginia Nurses Association, the focus in Virginia has traditionally, and in their view appropriately, been to pursue continuing education as a means of retaining specialty certification. However, unlike state licensure, specialty certification is voluntary as opposed to mandatory.

Recent Developments in the Regulation of Pharmacy Services in Virginia

A recent significant development in the regulation of pharmacy services in Virginia is the enactment of HB 1198 during the 2000 Session. This legislation authorizes any person who proposes to use a process or procedure related to the practice of pharmacy that is not expressly authorized by statute or regulation to apply to the Board of Pharmacy for such approval. Applications may only include new processes or procedures, within the current scope of the practice of pharmacy that relate to the form or format of prescriptions, the manner of transmitting prescriptions or prescription information, the manner of required recordkeeping, the use of unlicensed ancillary personnel in the dispensing process, and the use of new technologies in the dispensing process.

In recent years, the Board of Pharmacy has amended its regulations to authorize new practices to reflect new developments in the practice of pharmacy. This has included the use of automated data processing systems for prescriptions, transmission of prescription orders by fax machine and electronically, and the use of unit dose drug dispensing systems. DHP management believes that HB 1198 will result in applications to use different types of new technology (i.e. robotics) to support drug dispensing, as well as applications for different ways to utilize unlicensed pharmacy technicians.

Managed Care Health Insurance Plans (MCHIPs) Are Required to Obtain a Certificate of Quality Assurance from the Virginia Department of Health

In January 2000, the Virginia Department of Health promulgated regulations for certification of quality assurance for managed care health insurance licensees. Essentially, the regulations require each plan to have a quality assurance program in place so that appropriate issues are self-identified and adequately addressed. MCHIPs are required to apply for its certificate of quality assurance from VDH every two years.

One of the key regulatory requirements is that the MCHIP integrate "the quality improvement activities of all other organizational units, providers, delegated health service providers, and the governing body into the quality improvement program" and provide feedback to those entities. The quality improvement program is required to include the establishment of a system for review of providers' credentials, recredentialing, performance reviews and obtaining information about any disciplinary action against the provider. The MCHIP is also required to have a system for the evaluation of the outcomes and processes of clinical care services delivered to its enrollees.

Hospitals Have Internal Incident Reporting Systems That Are Linked to Their Quality Assurance and Risk Management Functions

All hospitals have some type of an internal reporting system that permits hospital staff to report various types of incidents and occurrences that represent a "variance" (i.e. a patient fall, suicide, medication error, etc.) from established policies and procedures. Hospitals typically use a pre-printed incident reporting form that staff are supposed to fill out and submit whenever they commit or witness a reportable incident. The systems that are in place can often differ from one hospital to the next in terms of the types of incidents that are included on the form for reporting purposes, and how various types of incidents are defined. Hospitals can also differ in terms of how the reported information is used. Hospitals typically use the reported information to support their internal quality assurance and/or risk management programs, by identifying trends and developing appropriate responses to prevent the future recurrence of such incidents. However, management personnel in some hospitals may also use the information as the basis for disciplinary action against staff members who were involved with the reported incident.

Virtually all of the respondents to the JCHC survey of hospitals reported that they currently have an internal incident reporting system that is administered and operated in a non-punitive manner. Furthermore,

the vast majority of respondents stated that incidents that are required to be reported are in fact reported either "always or very frequently" (20 percent) or "most of the time" (57 percent). However, many respondents also cited a number of factors which they believe serve as barriers to the internal reporting of incidents and occurrences by hospital employees and physicians. Among the most frequently cited barriers were:

- an assumption that the reported information would in fact be used in a punitive manner (i.e. job loss or other reprisal), coupled with a desire not to get co-workers or physicians in trouble ;
- lack of knowledge concerning the types of incidents that are supposed to be reported, coupled with overly complicated reporting forms and a cumbersome reporting process;
- lack of feedback to employees concerning how reported information has been utilized, which promotes a belief that reporting will not make a difference or result in any changes to the system;
- lack of time to complete the incident report, given other demands on staff time (i.e. patient care);
- a culture of blame within the institution, coupled with a belief among physicians that they do not make mistakes and that it is not their responsibility to report errors to the hospital, and
- concerns about malpractice litigation and legal liability.

Information Provided to or Produced by a Hospital's Risk Management or Quality Assurance Structure is Generally Protected From Discovery in Litigation, But There Are Exceptions

In Virginia, the basic statutory provision is that information provided to, or produced by, a hospital's internal risk management or quality assurance function is protected from legal discovery. Section 8.01 – 581.17 of the *Code of Virginia* states as follows:

> The proceedings, minutes, records and reports of any (i) medical staff committee, utilization review committee, or other committee as specified in §8.01-581.16 and (ii) nonprofit entity that provides a centralized credentialing service, together with all communications, both oral and written, originating in or provided to such committees or entities, are privileged

communications which may not be disclosed or obtained by legal discovery proceedings unless a circuit court, after a hearing and for good cause arising from extraordinary circumstances being shown, orders the disclosure of such proceedings, minutes, records, reports, or communications. Nothing in this section shall be construed as providing any privilege to hospital medical records kept with respect to any patient in the ordinary course of business of operating a hospital nor to any facts or information contained in such records nor shall this section preclude or affect discovery of or production of evidence relating to hospitalization or treatment of any patient in the ordinary course of hospitalization of such patient.

Section 8.01-581.16 of the *Code of Virginia* states as follows:

Every member of, or health care professional consultant to, any committee, board, group, commission or other entity shall be immune from civil liability for any act, decision, omission, or utterance done or made in performance of his duties while serving as a member of or consultant to such committee, board, group, commission or other entity, which functions primarily to review, evaluate, or make recommendations on (i) the duration of patient stays in health care facilities, (ii) the professional services furnished with respect to the ...necessity for such services, (iii) the purpose of promoting the most efficient use of available health care facilities and services, (iv) the adequacy or quality of professional services, (v) the competency and quality for professional staff privileges, or (vi) the reasonableness or appropriateness of charges made by or on behalf of health care facilities...

Legal representatives of health care providers in Virginia have cited what was described as "judicial confusion and inconsistency as to precisely what materials are entitled to the protection of the statute." For example, while committee minutes and credentialing information have generally been protected from discovery, there have been a wide range of judicial decisions concerning the discoverability of other types of materials that relate to a provider's quality assurance and/or risk management activities.

The majority of circuit court decisions, reaching back to the late 1980's, continue to uphold the peer review privilege. However, circuit courts in Fairfax County, Norfolk, Richmond City, and Roanoke City have granted plaintiffs access to hospital policies, protocols, procedure manuals and guidelines. In these cases, while questioning the ultimate admissibility of the documents, discovery has been allowed on the theory

that the documents are not "proceedings, minutes, records, or reports of committees." Several circuit courts (Charlottesville, Fairfax County, and Virginia Beach) have also permitted discovery of internal incident or quality control reports, at least to the extent of the reports' purely factual content. In general, courts ordering disclosure have often relied, at least in part, on the "ordinary course of business" exception to §8.01-581.17. The Alleghany Circuit Court has ordered the production of summary reports concerning serious incidents and unexpected deaths.

Defense attorneys express concern that such decisions "are likely to lead health care professionals to be reluctant to fully disclose adverse events in the fear that their report will later be used personally against them in a professional negligence action." This is portrayed as being inconsistent with the goal of creating an environment to enhance adverse event reporting and analysis. Without additional discovery protections built into any new mandatory reporting system, it is feared that the tort liability system and the public regulatory system will become inappropriately intertwined.

The Virginia Supreme Court in a June, 2000 opinion, (HCA v. Levin, June 9, 2000) for the first time issued an interpretation of §8.01-581.17 of the *Code of Virginia*. First, according to the Virginia Supreme Court, the privilege provided to the statute is not limited in its applicability to medical malpractice actions. Furthermore:

> The obvious legislative intent is to promote open and frank discussion during the peer review process among health care providers in furtherance of the overall goal of improvement of the health care system. If peer review information were not confidential, there would be little incentive to participate in the process.

For their part, members of the Virginia Trial Lawyers' Association who represent plaintiffs in medical malpractice cases believe that the current statutory provisions are excessive and prone to abuse by health care providers. One plaintiff's attorney interviewed by JCHC staff characterized the current statutory provision as "a liability shield in large measure, used to prevent people from bringing lawsuits." Another plaintiff's attorney interviewed by JCHC staff stated that certain "facts" concerning medical treatment are not always included in a patient's medical record – which is not shielded from discovery – and instead included in an internal incident report – which is generally protected from discovery. One defense attorney interviewed by JCHC staff stated that hospital incident reports have become increasingly "sanitized" due to concerns that the privilege will not be upheld. Plaintiffs' attorneys express

concern that expansion of the current peer review statute would be counterproductive to the interests of individuals who have been injured in the course of receiving health care services. They also express skepticism as to whether the existing peer review protections have resulted in any significant quality or safety improvements within the health care delivery system.

Virginia's State Health Data Reporting System Collects Certain Types of Data Related to Patient Safety

Virginia's health care data reporting system, established by §32.1-276 et. seq. of the *Code of Virginia*, has among its statutory objectives the development and dissemination of health care quality information designed to assist businesses and consumers in purchasing health care services. Section 32.1-276.6 of the *Code of Virginia* establishes 15 required patient level data elements that hospitals must report. One of the required data elements is "external cause of injury." Pursuant to this required data element, hospitals are to report, in appropriate cases, an ICD-9 (International Classification of Diseases, 9th Edition) code identifying a specific type of injury. Virginia Health Information (VHI), which collects, analyzes, and publishes the data, has no statutory authority to audit the reported data in any way.

There are hundreds of ICD-9 codes, all of which provide information which helps to explain to third-party payers why a particular patient has been hospitalized for a particular period of time. The codes reflect the fact that an individual may be hospitalized as the result of either disease, self-inflicted injury, or externally-inflicted injury. Certain codes (called "e-codes") pertain to specific types of events that are related to the provision of medical care, represent externally-inflicted injuries, and could most likely occur only within the context of a health care delivery setting. These codes are grouped into the following categories:

- misadventures to patients during surgical and medical care;
- drugs, medicinal and biologic substances causing adverse effects in therapeutic use; and
- surgical and medical procedures as the cause of abnormal reaction of patient or later complication, without mention of misadventure at the time of procedure.

Based on an analysis of the state's patient level database, administered by Virginia Health Information, Inc., for the years 1997 and 1998, surgical misadventures and adverse drug effects occur in a small, but

perhaps slightly increasing percentage of inpatient hospitalizations (Figure 8). Within the medical and surgical misadventures category, the specific types of events with the highest number of reported cases were:

Figure 8
Medical/Surgical Misadventures, Abnormal Reactions, and Adverse Drug Effects in Virginia Hospitals

	1997		1998	
	Number of Cases	Percent of All Inpatient Discharges Reported to VHI	Number of Cases	Percent of All Inpatient Discharges Reported to VHI
Medical/ Surgical Misadventures	553	0.07%	704	0.08%
Surgical and Medical Procedures as the Cause of Abnormal Reaction	8,834	1.11%	9,813	1.21%
Adverse Drug Effects	20,666	2.61%	22,216	2.76%

Source: JCHC staff analysis of patient level data provided by Virginia Health Information, Inc.

- code 870.0 - accidental cut, puncture, perforation or hemorrhage during a surgical operation (296 cases in 1997 and 331 cases in 1998);

- code 870.8 - accidental cut, puncture, perforation or hemorrhage during other specified medical care (52 cases in 1997 and 72 cases in 1998); and

- code 876.9 - other unspecified misadventures during medical care (17 cases in 1997 but 135 cases in 1998, of which 109 were from the Southwest Virginia Regional Health Planning Area).

Within the adverse drug effect category, the specific types of events with the highest number of reported cases were:

- code 932.0 – adrenal cortical steroids (2,099 cases in 1997 and 2,567 cases in 1998);

- code 933.1 – antineoplastic and immunosuppressive drugs (2,050 cases in 1997 and 2,175 cases in 1998); and

- code 942.1 – cardiotonic glycosides and drugs of similar action (1,537 cases in 1997 and 1,730 cases in 1998).

In terms of evaluating patient safety and adverse medical events, E-code data do have limitations. An e-code reported for a patient does not by itself prove that a preventable adverse medical event or medical error has occurred; nor does it indicate whether patient harm resulted from the event, or the extent of that harm. Furthermore, an e-code does not provide any information concerning the underlying cause of the event. That necessary level of detailed information can only come from review of medical charts, and associated forms of medical evidence.

Nevertheless, these data do suggest areas for greater review and analysis for the purpose of improved recognition, understanding and prevention of adverse medical events and medical errors. Furthermore, greater evaluation is warranted concerning whether the VHI patient level data base could be used, either in its present form or with some modification, as the basis for greater screening and surveillance, from a public health and health care purchasing perspective, of adverse medical events and medical errors in Virginia.

Among the respondents to the JCHC survey of hospitals, 46 percent agreed with the statement that "Data currently reported by hospitals to the patient level data base maintained by Virginia Health Information concerning certain types of externally-caused injuries (E-codes E870 –E879 and E930 – E949.9) have potential value as a basis for evaluating the nature and extent of adverse medical events in Virginia." Thirty-two percent of respondents disagreed, while 25 percent had no opinion. The National Association of Health Data Organizations (NAHDO) has proposed expanding the e-code for external cause of injury, so as to collect more detailed information concerning where within the health care delivery system the injury occurred.

V.
Public Policy Approaches To Patient Safety in Other States

Numerous Legislative Proposals Intended to Address Patient Safety and Medical Error Issues Have Been Introduced During 2000 In Other State Legislatures

In the aftermath of the IOM report, approximately 40 pieces of legislation have been introduced in state legislatures during 2000. For example:

- Washington: legislation was signed into law (1) authorizing the state health department to release medical error data for each hospital (which is already required to be reported to the health department); (2) requiring the department of health, in cooperation with the board of pharmacy and professional licensing boards, to develop recommendations for reducing medication errors; and (3) authorizing the department of health to review and audit the records of a hospital quality improvement or peer review committee in connection with its inspection and review of hospitals.

- Florida: legislation has been introduced requiring hospitals to report medical errors to the state agency for health care administration, which would then be made available to the public via the Internet.

- New York: legislation has been introduced requiring the commissioner of health to establish a patient safety center and to collect information on medical error reduction. The legislation requires the center to study all existing medical errors reporting requirements and to develop recommendations to consolidate data collection and eliminate duplicate reporting requirements. The center is also required to develop a voluntary and collaborative reporting system for the purpose of developing and disseminating best practices. The legislation further requires the center to utilize medical record data to recommend statewide medical safety goals, track the progress of providers in meeting the goals, identify systemic problems leading to medical errors,

with reporting systems. Most states do not have the authority or ability to create incentives to encourage greater reporting.

- Using medical error reporting data to improve public safety is still an issue with which states are grappling. A few states are using the reported data to develop quality improvement projects. One of these states is Massachusetts, in which the state department of health is collaborating with the other members of the statewide medical error prevention coalition.

In order to gain a better understanding of the costs and benefits of mandatory reporting systems, JCHC staff conducted its own telephone interviews with representatives of several of these states. Information collected from several of these interviews is summarized below:

South Carolina has had a mandatory reporting requirement for several years. However, the state health department is only in the beginning stages of development of an integrated data system that will allow better management of the data, and ultimate use of the data to foster improvements in quality and educational systems within the regulatory and provider communities. Ultimately, this should provide greater protection to consumers and the public. Currently, reports are reviewed by professional staff to identify the need for review or investigation of specific instances, and to identify trends specific to licensed activities.

* * *

New York has had a mandatory reporting system for 15 years, and it has gone through several iterations. The system was implemented by the health department as part of medical malpractice reform legislation. New York spent approximately $160,000 for the latest redesign of the system, and expects to spend about $50,000 annually for software and hardware upgrades. A key benefit of the reporting system is that it allows hospitals access to the data, so that they may perform their own peer review comparisons and trend analyses. Reported information is analyzed and fed back to hospitals in the form of newsletters and alerts by the department of health. New York reports that it has received positive feedback from hospitals concerning the system. A statewide council, containing provider representatives, provides direction to the reporting system.

* * *

Florida's mandatory reporting requirement was implemented as part of legislation requiring all hospitals to implement risk management programs with state oversight. The state health department believes that its mandatory reporting system provides at least some level of assurance that procedures designed to

minimize the occurrence of injuries are implemented and followed in facilities. In the recent past, there have been questions concerning JCAHO's reliability in looking over the shoulder of a facility's peer review function. Florida spends about $350,000 annually to analyze incoming reports, survey facilities, and license risk managers. Florida believes it would be beneficial for each state to have some type of system that monitors medical error issues and how facilities and providers are taking actions to minimize patient injury.

* * *

Washington uses its mandatory reporting system as a means to develop trend information across the hospital industry, and to work closely and collaboratively with the industry to ensure that adverse events are being addressed. The reporting system was implemented over a four-year period as a result of legislatively-mandated regulatory revision. The information required to be reported is fairly minimal (eight items), and the state health department does not yet maintain the reported information in a database. This regulatory revision included the development of standards that are consistent with JCAHO accreditation standards but much less extensive. According to Washington officials, the added value of its reporting system is that non-JCAHO accredited hospitals are effectively held to the same standards as accredited facilities. Washington noted that JCAHO accreditation is voluntary, and information is not available to the public. Washington is not sure that it is reasonable to assume that compliance with JCAHO standards results in the public being protected.

NASHP believes that issues concerning patient safety and medical errors are gaining increased prominence in state legislatures. NASHP is continuing to study the reporting systems in these states, as well as other efforts that are being made within those states to address patient safety issues. It will conduct extensive site visits to eight states during the Summer of 2000, and plans to issue a final report in January 2001.

The North Carolina Board of Pharmacy Requires the Reporting of Deaths Attributable to Prescription Drugs

Since 1992, the North Carolina Board of Pharmacy (NCBOP) has required that pharmacist-managers or owner representatives must report any information that suggests that a prescription drug or a device dispensed from a location holding a permit has caused or contributed to the death of a patient. North Carolina is the only state in the country with this type of reporting requirement. If the report of an incident leads to action by the NCBOP, filing of the report prior to the investigation will be seen as a mitigating factor; however, failure to file a report could be treated as an aggravating factor. According to NCBOP, "a report is not a confession as very few of the cases reported result in Board action." The

identity of the person filing the report is not disclosed, and reports are not released except as required by law.

A total of 162 deaths have been reported since 1992, or an average of about 20 per year. Since 1992, the number of deaths reported each year has tended to increase. According to the Executive Director of NCBOP, it is likely that this is partially a result of improved awareness of the requirement among pharmacists. However, the growing number of powerful prescription drugs on the market could also be a factor. Most of the reported deaths have come from hospitals as opposed to non-hospital settings such as community pharmacies. The NCBOP reports that that is probably to be expected. However, pharmacists in non-hospital settings also need to be aware of any drug-related problems that may arise in their patients.

Based on its analysis of the reported data, the NCBOP determined that only 11 percent of the death reports received since 1997 involve controlled substances, whereas 23 percent of death reports received prior to 1997 did involve controlled substances. According to NCBOP, since controlled substances comprise about 10 percent of all prescriptions, these report data indicate that their use in health care is not any more dangerous than other drugs.

The New Jersey Board of Medical Examiners Has Developed a Medical Error Reduction Plan

Along with requirements for two additional years of post-graduate training and continuing medical education, the New Jersey Board of Medical Examiners has proposed a mentoring and training program for physicians "whose skills have grown rusty or out-of-date in a particular area." This is an attempt to address complaints against doctors that are not serious enough to justify suspension or revocation of medical licenses, but that often lead to costly litigation. The president of the medical board has stated that "Our profession is going to undergo a lot more scrutiny in this area. The board, in this initiative, is ahead of the pack, being proactive." The board has received little opposition to the proposed reforms.

There Are a Wide Range of Potential Responses by the State of Virginia to the IOM Recommendations

Historically, there have been a few broad components of quality assurance in health care: self-regulation by hospital credentialing committees, malpractice litigation, and external regulation by licensure boards (including state and federal review of patient complaints to resolve

problem issues, systems, and practitioners); as well as state and federal requirements for continuous quality improvement processes. A key public policy question for Virginia is: Are these existing components sufficient, or does the public sector need to expand or somehow refocus its oversight of the health care delivery system to ensure that patient safety is being adequately addressed and safeguarded?

Virginia could respond to the IOM recommendations within the context of its various roles of regulator, purchaser, provider, educator, and provider of public information. In determining how to respond to the IOM recommendations, the range of possible legislative and regulatory actions by the federal government should be considered. However, it is still too early to determine exactly what types of measures the federal government will implement. For example, all hospitals could be required to implement patient safety programs as a condition of Medicare participation. Health care providers could be required to participate in a nationwide adverse event reporting system as a condition of Medicare participation. The National Quality Forum may issue recommended definitions and performance measures for terms such as medical error and adverse event. Activities at the federal level need to be closely monitored, so that their potential impact on Virginia's health care delivery system can be assessed.

The desirability of utilizing available Virginia-specific data, such as that contained in the patient level database maintained by VHI pursuant to a contract with VDH, should be considered as a guide to the development of state-specific policy initiatives concerning patient safety and medical errors. While a case could be made for basing policy proposals on the existing body of empirical research, analysis of Virginia-specific data could help develop policy initiatives better tailored to particular characteristics of this state. The desirability of making better use of this existing reporting system and database to promote patient safety, as opposed to seeking the same objective through implementation of a new, additional state reporting system, should also be considered.

The extent to which the state's response to the IOM recommendations should focus on regulatory approaches, collegial/collaborative approaches, or a balance between the two should also be considered. The ultimate public policy objective should be framed as the promotion and improvement of patient safety across all health care delivery settings. Virginia's current oversight structure, administered by VDH and DHP, contains some elements of both types of approaches but is predominantly regulatory in nature. Ninety-three percent of the respondents to the JCHC survey of hospitals agreed with the following statement: "The State of Virginia should modify its current system of

health care regulation to provide for greater collaboration with health care providers concerning the identification and dissemination of best practices for the promotion and protection of patient safety." On the other hand, only 29 percent of respondents agreed that "The State of Virginia should modify its current system of health care regulation to provide greater attention and focus to issues concerning patient safety."

Finally, legal ramifications associated with the reporting of data concerning medical errors and adverse medical events to the state need to be considered. In other states, a key obstacle to achieving compliance with mandatory reporting requirements lies in the difficulty of asking providers to volunteer information that could put them at risk of regulatory investigation or malpractice litigation. In Virginia, 51 percent of the respondents to the JCHC survey agreed that a Virginia-specific voluntary reporting system for medical errors or adverse medical events that result in death or serious harm would help to enhance public safety, so long as certain information was protected from public disclosure. Such a system would be consistent with the type of voluntary system advocated by the IOM report. Removing the threat of consequences may encourage members of the health care delivery system to more fully report and evaluate system failures that call patient safety into question. However, in so doing, care needs to be taken so as not to decrease existing incentives for personal vigilance, accountability, and responsibility.

VI.
Policy Options

The following policy options are offered for consideration by the Joint Commission on Health Care regarding the promotion of patient safety in Virginia, and implementation of the IOM report recommendations. However, these policy options do not represent the full range of options that the Joint Commission on Health Care may wish to pursue with regard to patient safety issues. Furthermore, these policy options are not mutually exclusive. The Joint Commission on Health Care may choose to pursue two or more of these options.

Option I: **Take no action**

Option II: **Introduce a joint resolution encouraging Virginians Improving Patient Care and Safety to (1) expand its membership to include representatives from the Department of Health Professions, the Department of Human Resource Management, the Department of Medical Assistance Services, the Medical College of Virginia, the University of Virginia Health Sciences Center, and Eastern Virginia Medical School; (2) examine the feasibility and potential benefit of using the Virginia Patient Level Database to help identify and analyze the occurrence of adverse medical events and medical errors; and (3) advise the General Assembly on the status of its efforts to address the issues of patient safety and medical errors.**

Option III: **Introduce a joint resolution requesting the Virginia Health Information Board of Directors to (1) examine the feasibility of adding "e-code" information to one of its existing publications or creating a new publication containing such information and (2) examine the feasibility of expanding the reporting of "e-codes" as recommended by the National Association of Health Data Organizations.**

Option IV: **Introduce legislation, and an accompanying budget amendment, directing the Department of Health to (1) develop information, utilizing data contained in the patient level data base maintained by Virginia Health Information, concerning the extent and nature of adverse medical events and medical errors; and (2) use the**

information to work in collaboration with health care providers to encourage patient safety improvements to the health care delivery system and, if necessary, incorporate the information into its regulatory programs. This legislation could contain a second enactment clause directing the Department of Health to review its regulations and on-site inspection procedures to ensure that they specifically address patient safety and medical error prevention and reduction issues. [*This approach would require access to medical expertise, perhaps through a contract with an organization such as the Virginia Health Quality Center, as well as defining of terms such as "adverse medical event" and "medical error."*]

Option V: Introduce legislation, and an accompanying budget amendment, directing the Secretary of Health and Human Resources to establish a voluntary system for the reporting and analysis of data concerning adverse medical events and medical errors. The purpose of this system would be to support the development and dissemination of best practices for the prevention of adverse medical events and medical errors. [*This option could be structured to locate the reporting system in a private sector organization, and protect the data contained in individual reports from disclosure and legal discovery, while at the same time authorizing the public disclosure of certain information developed from the reported data. This option would require defining terms such as "adverse medical event" and "medical error"*]

Option VI: Introduce legislation, and an accompanying budget amendment, directing the Virginia Department of Health Professions to develop an educational and outreach program for licensed and certified health care professionals designed to (1) disseminate best practices for the promotion of patient safety and the prevention of medical errors, and (2) promote formal collaboration between the public and private sectors in the promotion of patient safety.

Option VII: Introduce legislation directing the Department of Health Professions to promulgate regulations for the continuing education of licensed physicians, nurses, and pharmacists that specifically address the promotion of patient safety and the prevention of medical errors. [*This option would*

establish continuing education requirements for the Board of Nursing, and would modify existing continuing education requirements for the Boards of Medicine and Pharmacy]

Option VIII: Introduce legislation requiring all individuals licensed by Virginia's health regulatory boards to report unprofessional, incompetent, or substandard conduct or care by any other individual licensed by the same board; and providing immunity to any such individual who makes a report from criminal or civil liability resulting from such report. *[This option would implement a 1999 recommendation of the Joint Legislative Audit and Review Commission.]*

Option IX: Introduce legislation requiring the Department of Medical Assistance Services and the Department of Human Resource Management to specifically incorporate the promotion of patient safety and the prevention of medical errors into their health plan and provider contract provisions relating to quality of care and quality improvement.

Option X: Introduce legislation to amend §32.1-137.3 of the *Code of Virginia* directing the Department of Health to amend its regulations governing managed care health insurance licensees to specifically include the promotion of patient safety and the prevention of medical errors as part of the quality improvement requirements.

Option XI: Introduce a budget amendment, containing appropriate funding, directing the Medical College of Virginia, the University of Virginia Health Sciences Center, and Eastern Virginia Medical School to evaluate patient safety and medical error prevention issues and strategies in outpatient and physician office settings for the purpose of broadening the existing body of knowledge and best practices beyond the inpatient hospital setting.

APPENDIX A

004390824

HOUSE JOINT RESOLUTION NO. 9

Offered January 12, 2000

Prefiled January 6, 2000

Requesting the Joint Commission on Health Care to study the 1999 report of the Committee on Quality Health Care in America and the efficacy and appropriateness of implementing its findings and recommendations in the Commonwealth.

Patrons—Marshall and McDonnell

Referred to Committee on Rules

WHEREAS, pursuant to § 9-311 of the Code of Virginia, the Joint Commission on Health Care is to "study, report and make recommendations on all areas of health care provision, regulation, insurance, liability, licensing, and delivery of services"; and

WHEREAS, the Commission is to "endeavor to ensure that the Commonwealth as provider and regulator adopts the most cost-effective and efficacious means of delivery of health care services so that the greatest number of Virginians receive quality health care"; and

WHEREAS, studies have indicated that medical errors may account for the deaths of 44,000 to as many as 98,000 individuals in United States hospitals annually; and

WHEREAS, although medical errors may be more easily detected in hospitals, they occur in other health care settings as well, resulting not only in death, but in permanent disability and unnecessary suffering as well; and

WHEREAS, deaths from errors in medications may claim as many as 7,000 lives annually, exceeding the number of deaths attributed annually to workplace injuries; and

WHEREAS, according to "To Err Is Human: Building a Safer Health System," a 1999 report of the Committee on Quality Health Care in America sponsored by the Institute of Medicine of the National Academy of Science, the "health care delivery system is rapidly evolving and undergoing substantial redesign, which may introduce improvements, but also new hazards"; and

WHEREAS, the report notes that medication-related errors occur frequently in hospitals, and may include errors in prescribing and dispensing as well as patient nonadherence; and

WHEREAS, the Committee on Quality Health Care included a wide range of recommendations in its report, including the creation of a Center for Patient Safety to "develop knowledge and understanding of medical errors" and to evaluate "methods of identifying and preventing errors"; and

WHEREAS, also included among the Committee's recommendations were the establishment of a nationwide mandatory reporting system for these adverse medical events, the encouragement of voluntary reporting efforts, modifications to certain legal and confidentiality requirements to promote reporting and analysis, and the development of performance standards by health care organizations and health care professionals that focus greater attention on patient safety; and

WHEREAS, many of the recommendations and methods of implementation offered in this report have critical significance for the delivery of health care in the Commonwealth, and may present valuable insights that might be appropriately and effectively implemented within Virginia; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Joint Commission on Health Care be requested to study the 1999 report of the Committee on Quality Health Care in America and the efficacy and appropriateness of implementing its findings and recommendations in the Commonwealth. In conducting its study, the Joint Commission shall consult with health care providers, consumers, and insurers; examine current Virginia and national data regarding adverse medical events; review current patient safety initiatives in Virginia health care practices; and develop specific recommendations for the implementation of patient safety measures in Virginia.

All agencies of the Commonwealth shall provide assistance to the Joint Commission for this study, upon request.

The Joint Commission shall complete its work in time to submit its findings and recommendations to the Governor and the 2001 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

COMMONWEALTH OF VIRGINIA
HOUSE OF DELEGATES
RICHMOND

S. VANCE WILKINS, JR.
SPEAKER

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TWENTY-FOURTH DISTRICT

COMMITTEE ASSIGNMENTS
RULES, CHAIRMAN

March 10, 2000

Mr. Patrick W. Finnerty
Executive Director, Joint Commission on Health Care
Old City Hall, Suite 115
1001 East Broad Street
Richmond, Virginia 23219

Dear Mr. Finnerty:

During the 2000 Session of the General Assembly, the House Committee on Rules considered House Joint Resolution 9, patroned by Del. Robert G. Marshall, which directed the Joint Commission on Health Care to study the 1999 report of the Committee on Quality Health Care in America. In an effort to reduce the number of study resolutions, House Joint Resolution 9 was among those that were not reported. However, the House Rules Committee believes that the issues addressed by the resolution merit review. Therefore, the Commission is directed to undertake the study and to submit a written report of its findings and any recommendations to the Governor and to the 2001 Session of the General Assembly. It is requested that you notify Del. Marshall of any meetings that are scheduled by the Commission to consider the study issues, and that you regularly apprise the patron concerning the Commission's deliberations on such matters. Further, please note that this study request expires at the end of the 2000 legislative year. I am enclosing a copy of HJR 9 for informational purposes so that you may be informed of the objectives of the study.

Your cooperation and assistance in this matter are appreciated.

Sincerely,

S. Vance Wilkins, Jr.
Speaker

/bhe
Enclosure (HJR 9)
cc: The Honorable Robert G. Marshall
The Honorable Bruce F. Jamerson
The Honorable Susan Clarke Schaar

APPENDIX B

Policy Options Included in the HJR 9 Issue Brief

Option I: Take no action

Option II: Introduce a joint resolution encouraging Virginians Improving Patient Care and Safety to (1) expand its membership to include representatives from the Department of Health Professions, the Department of Personnel and Training, the Department of Medical Assistance Services, the Medical College of Virginia, the University of Virginia Health Sciences Center, and Eastern Virginia Medical School; (2) examine the feasibility and potential benefit of using the Virginia Patient Level Database to help identify and analyze the occurrence of adverse medical events and medical errors; and (3) advise the General Assembly on the status of its efforts to address the issues of patient safety and medical errors.

Option III: Introduce a joint resolution requesting the Virginia Health Information Board of Directors to (1) examine the feasibility of adding "e-code" information to one of its existing publications or creating a new publication containing such information and (2) examine the feasibility of expanding the reporting of "e-codes" as recommended by the National Association of Health Data Organizations.

Option IV: Introduce legislation, and an accompanying budget amendment, directing the Department of Health to (1) develop information, utilizing data contained in the patient level data base maintained by Virginia Health Information, concerning the extent and nature of adverse medical events and medical errors; and (2) use the information to work in collaboration with health care providers to encourage patient

safety improvements to the health care delivery system and, if necessary, incorporate the information into its regulatory programs. This legislation could contain a second enactment clause directing the Department of Health to review its regulations and on-site inspection procedures to ensure that they specifically address patient safety and medical error prevention and reduction issues. [*This approach would require access to medical expertise, perhaps through a contract with an organization such as the Virginia Health Quality Center, as well as defining of terms such as "adverse medical event" and "medical error."*]

Option V: Introduce legislation, and an accompanying budget amendment, directing the Secretary of Health and Human Resources to establish a voluntary system for the reporting and analysis of data concerning adverse medical events and medical errors. The purpose of this system would be to support the development and dissemination of best practices for the prevention of adverse medical events and medical errors. [*This option could be structured to locate the reporting system in a private sector organization, and protect the data contained in individual reports from disclosure and legal discovery, while at the same time authorizing the public disclosure of certain information developed from the reported data. This option would require defining terms such as "adverse medical event" and "medical error"*]

Option VI: Introduce legislation, and an accompanying budget amendment, directing the Virginia Department of Health Professions to develop an educational and outreach program for licensed

and certified health care professionals designed to (1) disseminate best practices for the promotion of patient safety and the prevention of medical errors, and (2) promote formal collaboration between the public and private sectors in the promotion of patient safety.

Option VII: Introduce legislation directing the Department of Health Professions to promulgate regulations for the continuing education of licensed physicians, nurses, and pharmacists that specifically address the promotion of patient safety and the prevention of medical errors. [*This option would establish continuing education requirements for the Board of Nursing, and would modify existing continuing education requirements for the Boards of Medicine and Pharmacy*]

Option VIII: Introduce legislation requiring all individuals licensed by Virginia's health regulatory boards to report unprofessional, incompetent, or substandard conduct or care by any other individual licensed by the same board; and providing immunity to any such individual who makes a report from criminal or civil liability resulting from such report. *[This option would implement a 1999 recommendation of the Joint Legislative Audit and Review Commission.]*

Option IX: Introduce legislation requiring the Department of Medical Assistance Services and the Department of Personnel and Training to specifically incorporate the promotion of patient safety and the prevention of medical errors into their health plan and provider contract provisions relating to quality of care and quality improvement.

Option X: **Introduce legislation to amend §32.1-137.3 of the *Code of Virginia* directing the Department of Health to amend its regulations governing managed care health insurance licensees to specifically include the promotion of patient safety and the prevention of medical errors as part of the quality improvement requirements.**

Option XI: **Introduce a budget amendment, containing appropriate funding, directing the Medical College of Virginia, the University of Virginia Health Sciences Center, and Eastern Virginia Medical School to evaluate patient safety and medical error prevention issues and strategies in outpatient and physician office settings for the purpose of broadening the existing body of knowledge and best practices beyond the inpatient hospital setting.**

Overall Summary of Comments

Ten commenters, Virginians Improving Patient Care and Safety, Virginia Pharmacists Association, The Medical Society of Virginia, the Virginia Department of Health Professions, Virginia Health Information, Virginia Association of Durable Medical Equipment Companies, Piedmont Liability Trust, Virginia Trial Lawyers Association, D'Anne Remocaldo, and Freeda Lynne Cathcart did not express clear, specific support or clear specific opposition to any of the stated policy options. However, these organizations did provide many constructive comments and recommendations. For example, Virginians Improving Patient Care and Safety stated that it would like to see a new policy option crafted that would be consistent with its core principles. The Virginia Trial Lawyers Association commented that none of the stated policy options would increase accountability for medical errors.

Among the other 9 respondents, the comments were varied in terms of support and opposition for the numerous policy options:

- None of the commenters expressed support for Policy Option I, while three commenters expressed specific opposition.
- Policy Options II and III were both clearly supported by three commenters. AARP expressed support for some of the elements in Policy Option II. VIPCS indicated general support for the concepts contained within Policy Options II and III, subject to certain recommended modifications. No one expressed opposition to Policy Option II, but one commenter did express opposition to Policy Option III.
- Policy Option IV was clearly supported by one commenter and clearly opposed by another. The Virginia Health Quality Center expressed support for some of the elements in Policy Option IV.
- Policy Option V was supported by two commenters and opposed by one. The Virginia Trial Lawyers Association expressed concern with a portion of this policy option.
- Policy Option VI was supported by two commenters and Policy Option VII supported by three commenters. No one expressed any specific opposition to Policy Options VI or VII.
- Policy Options VIII – XI were each clearly supported by three commenters. Policy Options VIII and XI were each opposed by one commenter. Policy Options IX and X were each opposed by two commenters. Several commenters, including VIPCS and the Virginia Nurses Association, recommended modifying Policy Option XI so that it would provide for a competitive grant process open to all interested health care organizations and providers.

Summary of Individual Comments

Virginians Improving Patient Care and Safety (VIPCS)

VIPCS is a coalition of approximately 25 health care organizations and providers, along with some consumer representation, who are interested in patient safety issues. Carl Armstrong, M.D. and Richard M. Hamrick, III, M.D., co-chairmen, stated that "while several of the policy options coincide with VIPCS' core principles we do not believe that any of the options, by themselves, are viable solutions." VIPCS "Core Principles for Addressing the Institute of Medicine's Report on

Medical Errors" were attached to its written comments. VIPCS did not express clear, specific support, or clear, specific opposition, to any of the policy options. However, the comments indicated relatively greater support for some of the options than for others.

With regard to Policy Option II, VIPCS would welcome the participation in the coalition of the other groups identified in the policy option. VIPCS would also be pleased to advise the General Assembly and the JCHC on the status of its efforts at any time. VIPCS agrees that an in-depth analysis of the feasibility and potential benefit of using the Virginia Patient Level Database to help identify and analyze the occurrence of adverse medical events and medical errors is appropriate in order to determine whether or not: (1) the database contains the necessary data elements and (2) the data are reported consistently and accurately statewide. The analysis would also assist in determining the impact of such reporting and the cost-effectiveness and efficacy of using the Patient Level Database for this purpose. VIPCS stated that it would commit its resources and the expertise of its members to such a study. However, VIPCS believes that such a study should be conducted by an independent organization with significant expertise in outcomes research and assessment, systems-based approaches to patient safety and risk-management, and the ability to evaluate and assess the appropriateness of the database for purposes. Funding would be necessary for such a study.

With regard to Policy Option III, VIPCS "concurs that e-codes may have some utility as a basis for evaluating the nature and extent of adverse medical events in Virginia and agrees that further analysis is appropriate. VIPCS stated that the analysis of e-codes should be incorporated into the study it recommended in response to Policy Option II.

VIPCS stated that it is premature to proceed with Policy Options IV or V prior to completion of the studies recommended in response to Policy Options II and III. VIPCS did state, in response to Policy Option V, that it may serve as a logical starting point for the dissemination of best practices information. VIPCS is also willing to conduct an inventory of existing reporting systems in order to aid in

the evaluation of potential reporting systems beyond the Patient Level Database.

In response to Policy Option VI, VIPCS stated that "it may have some value in the future." However, "many of the unresolved questions regarding patient safety and best practices must be addressed before the Department of Health Professions or any entity can effectively assume the extensive task of developing educational and outreach programs for licensed professionals and disseminating best practices for those professionals.

Concerning Policy Option VII, VIPCS "does not believe that mandating specific educational requirements establishes a sound precedent." While continuing education is one mechanism by which practitioners can improve their skills and abilities, it is essential that they retain the flexibility necessary to select and complete continuing education that best meets their professional goals and objectives.

In response to Policy Option VIII, VIPCS stated that "it supports in principle the reporting of any incompetent or substandard care by any individual." However, prior to extending this statutory mandate to all professions, the Department of Health Professions should "focus on raising awareness and compliance of existing requirements."

VIPCS stated that Policy Options IX and X are premature, since national accreditation organizations such as the National Committee on Quality Assurance, the Joint Commission on Accreditation of Health Care Organizations and the American Accreditation Health Care Commission are in the process of exploring the feasibility and advisability of incorporating patient safety into accreditation standards for managed care health insurance plans.

Concerning Policy Option XI, VIPCS stated that it "supports the establishment of a competitive grant process to evaluate patient safety and medical error prevention issues and strategies currently in place to broaden the existing body of knowledge and best practices for all settings, inpatient and outpatient." VIPCS believes that the grant "should be available to all potential, qualified

candidates or organizations that submit valid and competitive proposals."

VIPCS concluded by stating that, in order to ensure a coordinated, comprehensive approach to improving patient safety and enhancing the quality of health care for consumers, it would like to see a new option crafted that would be consistent with the VIPCS core principles and encompass:

- moving forward in studying the issues involved,
- identifying reporting systems that produce meaningful analysis of data for the purpose of learning and improving the quality of our health care system – to the extent possible this should focus on existing systems so as not to create duplicative effort
- the evaluation and analysis by an independent organization with the necessary clinical and systems expertise of any data submitted to a reporting system, and
- disseminating information to health care providers and consumers that is appropriate to their needs and enhances the quality of care.

Virginia Pharmacists Association

Rebecca Snead, Executive Director, did not express clear support or clear opposition to any of the stated policy options. However, VPA did express support for the response and recommendations provided by VIPCS. Ms. Snead also attached to her comments a position paper on the *Role of Pharmacists in the Medication Use System and Reducing Medical Errors*. This position paper includes, but is not limited to, the following statements:

- Any reporting system should provide "legal protection for confidentiality of patients, institutions, and health care workers to the extent feasible while preserving the interest of public accountability."

- Any reporting system should be non-punitive "in the sense that submission of a report, *per se*, does not engender a penalty on the reporting institution or practitioner or others involved in the incident."

- Another key participant within the medication-use process is the patient. If the public is educated on their role within the system many medication errors can be avoided.

Virginia Association of Durable Medical Equipment Companies

Rebecca Snead, staff to the association, did not express clear support or clear opposition to any of the stated policy options. However, Ms. Snead did express support for the response and recommendations provided by VIPCS.

The Medical Society of Virginia

Michael Jurgensen, Director of Health Policy, did not express clear support or clear opposition to any of the stated policy options. However, MSV did express support for the comments provided by VIPCS. Mr. Jurgensen also reiterated the point that "medical errors can be prevented and patient safety enhanced by taking a systems-intensive approach to the redesign of medical work."

Virginia Society of Health-System Pharmacists

Fred D. Chatelain, Legislative and Regulatory Affairs Chair, expressed support for Policy Options II, and IV – X. Mr. Chatelain also expressed support for Policy Option III but suggested that it be expanded to examine the feasibility of expanding the reporting database to include retail (outpatient) entities. "This would broaden the database to incorporate the full spectrum of health care. Without this addition, the reporting unfairly targets inpatient settings." Mr. Chatelain expressed opposition to Policy Option I.

Virginia Nurses Association

Rebecca Rice, EdD, RN, MPH, President, expressed support for Policy Options II, V, and VIII - X. VNA expressed opposition to Policy Option I.

Concerning Policy Option III, VNA supports an examination of the use of e-codes. Two potential problems with the use of e-codes were

described by VNA. First, they are limited to inpatient settings by current law. Second, as the JCHC issue brief states, an e-code does not by itself prove that an adverse event or a medical error has occurred.
The VNA noted that statistics from the Institute of Medicine report have been called into question in journal articles published in recent weeks. However, VNA also noted that "the disputed numbers may well argue for collection and analysis of additional Virginia-specific data."

VNA believes that Policy Option IV may be premature without further study. Concerning Policy Option VI, VNA believes it may be premature and "inappropriately focuses on the health care professional and not the system."

VNA opposes Policy Option VII as constituted. However, the VNA would support a "continued competence requirement that could be specified in regulations to be developed by the Board of Nursing." Under this suggested approach, the Board of Nursing would be allowed latitude in determining what evidence of continued education is appropriate.

VNA noted that, while it supports Policy Option VIII, "this should not be implemented in the hopes that it will resolve problems with medical errors since it focuses on individual providers. Since the vast majority of medical errors result from systemic failures and inadequacies, systemic solutions are required."

In response to Policy Option XI, VNA supports efforts to broaden the existing body of knowledge to include non-hospital settings. However, VNA believes this might be accomplished more cost effectively with "a competitive grant process rather than an automatic award to the medical schools."

Finally, the VNA stated that research "indicates an inverse relationship between nurse staffing levels and the incidence of post-operative adverse events." Thus, according to the VNA, there is also "a relationship between this Commission study and the study of the recruitment and retention of nurses." Furthermore, VNA suggests "that as options for data collection are considered, the Commission

may wish to ask that data be collected and reported on nurse staffing levels as well as medical errors and outcomes."

Virginia Association of Health Plans

Lynn Warren, RN, MPH, Director of Policy, stated that VAHP concurs with the comments and recommendations submitted by VIPCS. In addition, VAHP stated its opposition to Policy Options IX and X. VAHP stated that Virginia's current regulatory standards for managed care health insurance plans "are modeled after the industry's 'gold standards'" established by the NCQA and the URAC. Ms. Warren stated that NCQA, URAC, and JCAHO "have established a Patient Safety Steering Committee, which includes representatives from federal government, national profession and trade organizations, purchasers and consumers. The Committee is in the process of determining how to incorporate more specific patient safety criteria into existing accreditation standards. One of their challenges is to determine the critical distinctions between which patient safety activities fall into the health plans' domain versus the scope of practice of health care providers." VAHP believes that Policy Options IX and X are premature until the national accrediting bodies have completed their analysis; any resulting new patient safety standards have been tested in the marketplace; and, in the case of Policy Option X, DMAS and DPT have determined if such an initiative is feasible and advisable.

Trigon Blue Cross Blue Shield

Leonard L. Hopkins, Jr., Vice President, Public Policy Officer, expressed agreement with, and endorsed, the comments submitted by the Virginia Association of Health Plans.

Virginia Chapter of the American Society for Healthcare Risk Management (VASHRM)

Fred Schriever, President, expressed support for Policy Options II and VI. Mr. Schriever expressed opposition to Policy Options III – V and VIII – XI.

VASHRM supports expanding the focus of Policy Option II "to include proposals designed to invest in knowledge building about systems design and analysis that can be shared with hospitals and practitioners."
VASHRM does not support "any option in which legislation is proposed to elicit mandatory or voluntary reporting by hospitals of data relative to complications, errors, and/or incidents. Such wide-based reporting is overburdensome, inaccurate, and will not assist in promoting patient safety. For example, e-codes reflect medical complications, not 'near-misses', and are only occasionally the result of a process external to the patient. The use of this information would not accurately reflect safe practices or errors."

VASHRM supports "proposals to encourage the State's medical colleges to evaluate patient safety and medical error prevention issues and strategies, but not limited to outpatient and physician office settings."

VASHRM recommends "education programs for patients delineating their responsibilities in minimizing medical errors. Many hospitals and physician offices are already promoting this type of information for patients." Finally, VASHRM stated that "Reduction of medical errors can not be legislated. True patient safety and reduction of errors is accomplished through education, training, and sharing of best practices."

Piedmont Liability Trust

Judy L. Fortineux, ARM, Risk Manager, did not express clear support or clear opposition to any of the stated policy options. However, she did suggest a few items for consideration in the framework of promoting patient safety:

- Strengthened statutory protections for quality assurance activities, beyond those currently contained in §8.01-581.17, are needed.

- A non-punitive stance should be taken whenever possible by the Department of Health or the health regulatory boards in the course of conducting investigations.

- Existing reporting and monitoring systems, in particular the sentinel event reporting system established by JCAHO should be used rather than establishing new reporting requirements. JCAHO's efforts "should be coordinated with designated state bodies to effect the most efficient and complete quality process with input from all involved. New agencies, new regulatory bodies need not duplicate efforts. Rather, existing agencies need to strengthen and coordinate with other designated oversight organizations."

Virginia Health Information

Michael T. Lundberg, Executive Director, did not express support or opposition for any of the stated policy options. Mr. Lundberg did state that "VHI is pleased that the patient level data system it maintains is mentioned as a possible source of information to evaluate issues of patient safety and medical errors."

Virginia Department of Health Professions

John Hasty, Director, did not express support or opposition for any of the stated policy options. However, DHP did offer its perspective on the advantages and disadvantages of various policy options.

Concerning Policy Option VI, DHP stated that its mission is to "license competent practitioners; it has not actively and directly offered educational and outreach activities to its licensees." DHP noted that a charge to the department "to assume responsibility for providing educational programs would move the agency beyond its current mission with costs and manpower requirements that are unknown at this time. Some boards do approve providers of continuing education but no board currently is a provider itself."

In response to Policy Option VII, DHP stated that for those professions that currently have continued competency requirements, "there may be some advantage to addressing issues of patient safety and prevention of medical errors, so long as opportunities exist for the practitioner to choose learning activities that directly relate to practice." DHP also stated that "The Board of Nursing has studied the issue of continued competency requirements for its licensees and

concluded that the potential impact on patient care is not clearly apparent." However, "there may be some benefit to a requirement for a refresher course for nurses who have been out of practice or not actively practicing for some period of years." DHP noted that a general requirement for continuing education for nurses would create a fiscal impact on the Board of Nursing and on individual licensees. DHP raised the possibility that a continuing education requirement for nurses could "result in some nurses allowing their licenses to lapse thus exacerbating the existing shortage of nurses in the Commonwealth."

DHP expressed several concerns regarding Policy Option VIII. First, the extent of compliance with existing mandatory reporting requirements is unknown. DHP is also concerned about the possible consequences to a practitioner who, for whatever reason, failed to report on another practitioner. DHP believes "such a broad provision could be very difficult to enforce."

DHP also expressed concerns about Policy Option XI. While DHP acknowledges that acquiring and analyzing data from outpatient and physician office settings may be appealing, it has concerns about the application of the concept and the process for conducting the study. These concerns include the protection of confidentiality of individual patient records and the additional burden on health care practitioners for reporting and data collection. Also, other settings (i.e. long-term care facilities, home health agencies, and retail pharmacies) where patient errors occur with potentially serious consequences were not included in the Policy Option.

Finally, DHP noted that "Workload issues related to pressure to see more patients or fill more prescriptions in less time, to work double shifts when shortages exist, and spend longer hours on the job result in practitioner fatigue and heightened risk of error." Potential solutions to these issues need to be discussed before the issue of patient safety can be fully addressed. The Board of Health Professions has planned an Issues Forum for November 2000 to focus on the Institute of Medicine report and its implications.

Virginia Health Quality Center

Joy Hogman Rozman, Chief Executive Officer, expressed support for portions of Policy Option IV. VHQC supports, within Policy Option IV, the concept of collaboration with health care providers to encourage patient safety improvements to the health care delivery system. VHQC also supports the portion of Policy Option IV that calls for the Virginia Department of Health to review its regulations and on-site inspection procedures to ensure that they address patient safety and medical error prevention/reduction issues.

VHQC recommended that Policy Option IV be broadened to encompass additional existing data beyond that contained in the Patient Level Database. VHQC believes that would result in a more accurate and complete basis for improvement efforts.

VHQC also stated that it supports the general concept of a reporting system, either mandatory or voluntary. Finally, VHQC supports the recommendations of VIPCS regarding the attributes of a reporting system, including strict confidentiality for patients and providers; reports made to a non-regulatory, independent organization; adequate resources and feedback mechanisms provided; lack of duplication or burden on providers; and responsible public reporting.

AARP

Jack Hundley, Chairman, State Legislative Committee, stated that a combination of the various Policy Options may be the best approach. AARP expressed support for the portion of Policy Option II that involves examining the feasibility and potential benefit of using the Patient Level Database to help identify and analyze the occurrence of adverse medical events and medical errors. Also with regard to Policy Option II, AARP stated that if the General Assembly is planning to rely on VIPCS for continuing information on patient safety issues, "then a request for periodic reports on its efforts is appropriate."

AARP expressed support for Policy Option III, and recommended that it be combined with section (2) of Policy Option II. AARP believes that Policy Option IV may be appropriate and potentially

beneficial in the long-term, however, "using any existing data before completing the studies recommended in Options II and III may prove confusing and potentially misleading in the near term." Similarly, AARP also stated that Policy Option V is premature at this time. AARP does support the concept, mentioned in Policy Option V, of locating any such reporting system in a private sector organization. AARP stated that Policy Option VI would appear to have more value in the future when current data would be available.

Concerning Policy Option VII, AARP said that it supports continuing education for health care providers. AARP expressed concern about Policy Option VIII. If implemented, according to AARP, this option could produce some "bad" information and further encourage the "blame game" that is antithetical to the systems approach to medical errors.

AARP expressed support for Policy Options IX, X, and XI.

Dr. Susan Mead

Dr. Mead expressed opposition to Policy Option I. Concerning Policy Option II, Dr. Mead stated that there should be "significant representation of consumers" on VIPCS. Dr. Mead also noted that, if medical schools receive representation on VIPCS, then representatives of other educational programs and institutions that prepare health professionals should also be included.

Dr. Mead expressed support for Policy Option III. She said that Policy Option IV would be a positive step. However, "until the legal status of professions such as direct-entry midwifery are changed, accurate safety statistics for health care in Virginia will be incomplete."

According to Dr. Mead, the voluntary reporting suggested in Policy Option V "does not seem rigorous enough" and mandatory reporting seems much more desirable. She noted that development and dissemination of evidence-based best practices is essential. However, it is imperative that the full range of safe health care options must be considered, "whether or not presently allowed by the statutes of Virginia."

Dr. Mead stated that the educational and outreach programs suggested in Policy Option VI would be welcome.

Dr. Mead expressed support for Policy Option VII. She also expressed support for Policy Option VIII but with two major caveats. First, reporting should be required not only of professionals licensed by the same board, but also across different regulatory boards "since these professionals work so closely together in actual health care settings." Second, and more importantly according to Dr. Mead, legislators must "develop and build into the statute safeguards which prevent practitioners from making frivolous complaints based on professional or personal conflicts of interest (e.g. not recognizing certain procedures as legitimate across specialties.)"

Dr. Mead expressed support for Policy Options IX and X. She also expressed support for Policy Option XI, but suggested expanding it to include non-hospital care centers and home health care settings. Dr. Mead also suggested that the research contemplated by Policy Option XI be expanded to encompass work done by Virginia's nursing schools and other educational institutions.

Steve Cochran

Mr. Cochran indicated general opposition to Policy Option I. Concerning Policy Option II, Mr. Cochran noted that individual consumers or representatives of consumer organizations need to be added. Mr. Cochran stated that Policy Option III "seems to be a simple and logical step to take." Concerning Policy Option IV, Mr. Cochran stated that "I don't see that improving onsite inspections would contribute a great deal to solving problems that appear to be mainly practice related."

Mr. Cochran expressed concern about Policy Option V: "Voluntary efforts that envision a need to limit public disclosure would surely be a waste of time and effort, and taxpayers should be offended by every element of this suggestion." Mr. Cochran does not feel that Policy Option VI "represents any significant step beyond business as usual."

Mr. Cochran expressed strong support for Policy Option VII. He noted that Policy Option VIII "would make a lot of sense IF it were not limited only to practitioners who are licensed by the SAME board."

Mr. Cochran expressed support for Policy Option XI.

D'Anne Remocaldo

Ms. Remocaldo expressed general concern about the overall thrust of the policy options. "If Medicine is about helping people then where's the people in all these options? These options speak of the profession, what is convenient for them or how to get them to cooperate. If medicine is about helping sick, vulnerable, suggestible people then why all the opposition to LIFE SAVING changes to the system. We must ask if perhaps medicine is for the practitioners right to practice over the patient's right to safety."

Ms. Remocaldo also stated that "History has shown that those medical societies, hospital audits and government professional review boards are meaningless in bringing about positive change FOR THE GOOD OF THE PEOPLE."

Ms. Remocaldo stated that Policy Option III "has merit." She also said that Policy Option VIII would be one of the best options "if it weren't totally gutted by term 'same' board."

Freeda Lynne Cathcart, BA, FLMI, ICCE

Ms. Cathcart did not express clear support or clear opposition to any of the Policy Options. Included among her comments were the following statements:

"The general public seems unaware of the danger that a loved one may face if left alone with medical practitioners. They believe that the hospital and doctors will care for the entire health of their loved one. Often hospitals and doctors have different values than many people in the general public."

"Government paid independent patient advocates need to be added to the system immediately."

Virginia Trial Lawyers Association

Mark E. Rubin, Counsel, did not express clear support or clear opposition to any of the stated policy options. Mr. Rubin did comment that VTLA has requested that one of its members be included in the expanded membership of VIPCS, as proposed in Option II.

According to VTLA, there is a "glaring omission" from all of the policy options, in that none of them address "increasing accountability for medical errors." VTLA expressed the position that, due to current statutory cap on medical malpractice damage awards and due to the cost-prohibitive nature of bringing a medical malpractice action, "the legal system does not provide accountability for the vast majority of medical errors."

VTLA noted that while it is important to look at issue of patient safety systematically, "it is equally important to keep in mind that each of the statistics being reviewed is an individual who may have been harmed as a result of a medical error." Furthermore, according to VTLA, "Increasing patient safety by putting roadblocks in front of a patient who is seeking compensation for medical negligence unduly emphasizes the system's perceived need for secrecy over the individual's legitimate claim for medical care, lost wage replacement and compensation for loss in the patient's quality of life."

Consequently, according to VTLA, "Any option such as Option V which suggests that present immunity provisions for reporting medical errors should be expanded would constitute such a roadblock to an individual victim of medical malpractice."

JOINT COMMISSION ON HEALTH CARE

SUMMARY OF PUBLIC COMMENTS: Improving Access to Dental Care Study (HJR 198/HJR 296)

Organizations Submitting Comments

A total of 8 organizations and individuals submitted comments in response to the HJR 198/HJR 296 report on improving access to dental care in Virginia:

- Virginia Primary Care Association
- Virginia Association of Free Clinics
- Delta Dental Plan of Virginia
- Virginia Poverty Law Center
- Virginia Health Care Foundation
- Virginia Dental Hygienists' Association
- Virginia Dental Association
- Old Dominion Dental Society

Policy Options Included in the HJR 198/HJR 296 Issue Brief

Option I **Take No Action**

Option II **Introduce A Budget Amendment To Increase The Amount Of General Funds Appropriated For The Dental Scholarship And Loan Repayment Program**

Option III **Introduce A Budget Amendment To Increase Medicaid Reimbursement To Dentists To The 85th Percentile Of UCR**

Option IV **Introduce A Budget Amendment To Extend Dental Benefits To Adult Medicaid Eligibles. The Budget Amendment Could Request Coverage And Funding For: (I) General Dental Benefits Only; (II) Dentures Only; Or (III) Coverage For General Dental Benefits And Dentures.**

Option V **Introduce A Budget Amendment To Provide Additional General Fund Support To The Virginia Health Care Foundation To Be Used Specifically In Support Of Projects To Improve Access To Dental Care**

Option VI **Introduce A Joint Resolution Requesting The Virginia Department Of Health To Monitor The Continuing Research On The Safety Of Dental Amalgam And Report To The Governor And General Assembly In The Event Such Research Indicates The Use Of Dental Amalgam Poses A Health Risk**

Option VII **Send A Letter From The Chairman Of The Joint Commission On Health Care To The Virginia Health Care Foundation Requesting It Consider Sponsoring A Survey Of The Insurance Status Of Virginians To Provide More Current Information Regarding The Commonwealth's Uninsured Population**

Overall Summary of Comments

Option II received the greatest level of support with 6 of the 8 commenters expressing specific support for increasing the amount of funding appropriated for dental scholarships and loan repayment. Options IV and V were supported by 5 of the 8 commenters. Three commenters expressed clear support for Option III. Options VI and VII received less support among the commenters with only 3 supporting Option VII and 2 expressing support for Option VI. There

was very little specific opposition to any of the Policy Options. One comment was received in opposition to both Options IV and VI.

Three commenters, the Virginia Dental Hygienists' Association (VDHA), the Virginia Poverty Law Center (VPLC) and the Virginia Association of Free Clinics (VAFC) also commented in support of some policy options from last year's study that were not included in this report. The VDHA and VPLC expressed strong support for providing less restrictive supervision of dental hygienists. The VAFC commented that the Commonwealth should address legal and regulatory issues to ensure maximum participation of dental professionals in providing access to care. VDHA also commented in support of funding the dental hygienist scholarships. The VPLC commented in support of authorizing licensure by endorsement for dentists and increasing the salaries of public health dentists.

Summary of Individual Comments

Virginia Primary Care Association (VPCA)

The VPCA expressed support for Options II-V. In response to Option VII (replication of the 1996 survey of the insurance status of Virginians), the VPCA commented that although there may be slight changes in the uninsured population detected by the survey, it recommends that resources be used for direct dental services for underserved populations rather than an additional survey.

Virginia Association of Free Clinics (VAFC)

The VAFC expressed support for Options II, III, IV, and VII. In support of Option IV, VAFC favors dental benefits for Medicaid adults that includes both general dental benefits and dentures. The VAFC commented that the Commonwealth should invest substantial additional resources in developing and strengthening the dental care delivery system for the underserved. VAFC also commented that "in addition to more funding, the Commonwealth should address legal and regulatory issues to ensure maximum participation of dental professionals in providing access to dental care." Lastly, VAFC

indicated that it is important for both public and private entities to work together more effectively to develop solutions that will improve access to care, and that it is helping to facilitate the formation of a broad-based coalition to address dental care access issues.

Delta Dental Plan of Virginia (Delta)

Delta's comments included specific support of Options II and V. In support of Option V, Delta indicated that the additional support provided to the Virginia Health Care Foundation should address the need for additional education of the general public on the importance of good dental care and hygiene. With respect to Option III (increased Medicaid reimbursement for dentists), Delta indicated it neither opposes nor supports this action, and that further study of this issue may be required to determine an appropriate level of reimbursement. Delta expressed opposition to Options IV and VI.

In addition to commenting on the specific Policy Options, Delta also commented that it believes the number of actively practicing dentists stated in the report may be overstated, and that the number of dentists needed to eliminate shortages in underserved areas is significantly higher. Delta indicated that the number of dentists leaving active practice is increasing thereby reducing the number of "productive chair hours." In response to this concern, Delta identified three possible actions: (i) increase efficiency/ productivity through implementation of new technology and practice management systems; (ii) increase the dental school enrollment; and (iii) increase the availability of and expand the roles for dental auxiliaries.

Delta also commented that direct reimbursement of dentists increases the underlying cost of dental care which is contrary to the study's stated objective of improving access to care. Lastly, Delta suggested that consumer education of the importance of good dental care is "the critical first step to improving oral health among all Virginians, especially Virginia's children. The General Assembly might consider charging the Department of Education, working with the Department of Health, to evaluate, design, and implement

programs to educate Virginia's school-age children and the parents about the importance of good oral health."

Virginia Poverty Law Center (VPLC)

The VPLC commented in favor of Options II-V and VII. The VPLC also expressed strong support for easing the supervision restriction of dental hygienists. VPLC commented that "the best way to quickly increase the availability of dental services throughout the state is to allow dental hygienists to work outside the 'direct (physical) supervision' of dentists. . . Forty-five states have found an acceptable way to do this, and certainly Virginia can too." The VPLC also commented in support of authorizing licensure by endorsement for dentists. In support of this issue, the VPLC noted that "[C]onsidering the enormity of Virginia's underserved population, I support licensure by endorsement so long as it is tied to some kind of reasonable public service obligation." Lastly, the VPLC also expressed support for increasing the salaries of public health dentists.

Virginia Health Care Foundation (VHCF)

The VHCF did not express any specific support for any of the Policy Options; however, VHCF commented that it "would be honored and grateful to receive additional state money targeted to supporting community based dental initiatives. VHCF would bring the same responsible stewardship to any new funds that it brings to its current appropriation. In FY99, VHCF generated over $6 for every state dollar received. At the same time, 85% of VHCF's 'graduated' projects were sustaining themselves at a full level of operations for at least three years after VHCF funding." The VHCF concluded its comments by offering to help improve access to dental care in any way it can.

Virginia Dental Association (VDA)

The VDA specifically expressed support for Options II, V, VI, and VII. Regarding Option III, the VDA indicated that it applauds the

JCHC for putting the option forward to try to increase Medicaid reimbursement to the 85th percentile. VDA commented in response to Option IV that while providing dental coverage to Medicaid adults is an important issue, it "realizes that there are limitations within the budgetary process. It is going to be difficult for the General Assembly to increase funding, both for Medicaid services for children as well as for adults."

In addition to commenting on the specific Policy Options, VDA also provided information on several programs and activities it has been involved in to improve access to care. These programs/activities include: (i) the "Donated Dental Services" program, (ii) VDA members providing care at 20 Free Clinics, (iii) the Child Health Investment Program in Charlottesville, (iv) working to establish a coalition of various groups to advocate for improved access to dental care; and (v) outreach programs such as the recently completed "Mission of Mercy Project" in Wise County that took place in mid-July.

Virginia Dental Hygienists' Association (VDHA)

The VDHA commented in support of Options II-VII. In supporting Option VII, the VDHA noted that it "supports this option only to the extent that it does not detract from the Virginia Health Care Foundation's abilities to devote resources to dental projects which directly improve access to care."

In addition to commenting on the Policy Options included in the report, the VDHA also noted that "it finds the Draft Issue Brief glaringly deficient in its failure to take a closer look at the need for legislation to authorize less restrictive supervision of dental hygienists. . . Modification of this restriction is within the scope of this study, and it is one of the best ways of increasing access to care by many of the Virginians who are unable to obtain services that dental hygienists are qualified to provide. Continuation of the current restriction only exacerbates the dental care crisis among Virginia's underserved populations, so now is the time make a change." The VDHA also commented that "[A]nother element missing from the Brief is a policy option to support a budget amendment to fund dental hygiene scholarships. . . The VDHA urges the Joint

Commission to include such an amendment among the policy options it recommends."

Old Dominion Dental Society (ODDS)

The Old Dominion Dental Society commented in favor of Option IV. In its comments, the ODDS noted that "[W]ith poor mastication and gum disease the person can develop heart disease, strokes, intestinal problems, etc. Even if there is an additional cost to the state for adult dental care, there will also be a savings on medical care. I feel that Virginia should join the majority of states that provide some type of dental coverage for Medicaid adults."

JOINT COMMISSION ON HEALTH CARE

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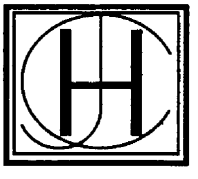

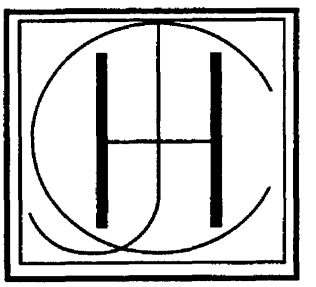

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