Preliminary Determination Package (Pre-NOIRA) for Promulgating Regulations, for the Certificate of Quality Assurance of Managed Care Health Insurance Plan (MCHIP) Licensees

Item 1: Specific Reason for the Regulation.

In House Bill 2785 (Acts of Assembly, Chapter 688, 1997), the General Assembly requested the State Health Commissioner to study the quality of health care services provided by health maintenance organizations (HMOs). The Commissioner's charge included: (i) examining and assessing the sufficiency of various mechanisms for assuring the quality of care provided by HMOs and professionals with whom they contract; (ii) determining whether such mechanisms should be extended to managed care entities other than HMOs; (iii) examining ways for the Virginia Department of Health (VDH) and the State Corporation Commission's Bureau of Insurance to collaborate in regulating managed care entities effectively; and (iv) identifying the appropriate role for VDH in monitoring the quality of health care provided by HMOs and other managed care entities.

The resulting report, presented by the Commissioner to the General Assembly and the Governor on October 1, 1997, noted that rapid shifts in the health care market have led consumers to demand improvements in the quality of care and in the level of protection afforded them by HMOs. The Commissioner's report, the culmination of months' of collaboration with interested and regulated groups, suggested that responding to this demand requires a deliberate effort, *i.e.*, legislation¹ establishing an impartial authority capable of validating, from a perspective informed solely by public health considerations, the quality of managed health care in general. Accomplishing this task would require devising a new category of managed care entities, to be known as managed care health insurance plan (MCHIP) licensees, drafting regulations that establish appropriate standards and requirements, and constructing a regulatory program designed to protect public health by certifying the quality of medical plans offered by MCHIP licensees.

<u>Item 2: Source of Legal Authority to Promulgate: Source and Scope of the Mandate.</u>

Senate Bill 712 (Acts of Assembly, Chapter 891, 1998) implements the lessons learned during the six months in which the Commissioner prepared the HB 2785 report. Effective July 1, 1998, SB 712 will amend the *Code of Virginia* by inserting two articles -- Articles 1.1 and 1.2 -- in Chapter 5 of Title 32. 1.

Article 1.1, *i.e.*, Section 32.1-137.1 through 32.1-137.6, will authorize the State Board of Health and the State Health Commissioner to implement a program for certifying the quality of

¹ This legislation took the form of Senate Bill 712 (Acts of Assembly, Chapter 891, 1998), patroned by Senator Martin and approved by the governor on May 19, 1998, which is discussed in some detail below.

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managed care health insurance plan licensees. Specifically, Section 32.1-137.3 will direct the Board, "[c]onsistent with its duties to protect the health, safety, and welfare of the public," to promulgate regulations "governing the quality of care provided to covered persons by ... [an MCHIP] licensee through its managed care health insurance plans on or before December 1, 1999."

(Article 1.2, *i.e.*, Section 32.1-137.7 through 32.1-137.17, will establish standards for decisions regarding utilization review² made by MCHIP licensees and for appeals from those decisions. This article authorizes the Commissioner to determine compliance with the article, but will not authorize the State Board of Health to promulgate regulations carrying out these particular standards.)

Item 3: Reasoning for Concluding the Contemplated Regulation is Essential.

With the expanding influence of managed health care, the numbers of MCHIPs and persons enrolled in them will increase, and the need for standards assuring the quality of services provided by MCHIP licensees will intensify. The contemplated regulations will allay public concerns over quality in the managed health care market by, among other things, establishing protective standards and providing a process for the redress of complaints against MCHIP licensees.

In 1980, Virginia enacted a law that introduced licensure of and operating requirements for HMOs. *See* Section 38.2-4300 *et seq.* of the *Code*. This law seeks to ensure the basic financial soundness of HMOs, but fails to include requirements that directly protect public health. Originally, this law gave the State Health Commissioner discretionary authority to examine the quality of health care services and the complaint systems of HMOs; HB 2785 (1997), discussed above, made this authority mandatory. In addition, HB 2785 charged VDH with the responsibility of receiving and responding to quality of care complaints from managed care enrollees.

SB 712 (1998) establishes a quality assurance certification program for HMOs and other entities that fit the definition of an MCHIP licensee. All MCHIP licensees will have to obtain certification and remain certified by the Commissioner to confirm the quality of health care services they deliver. The contemplated regulations are essential in order to provide critical detail to carrying out the intent of the law, as it will be amended by SB 712, and to define the expectations relating to quality and upon which certification of MCHIP licensees will be based.

² Utilization review is a technique involving the examination and evaluation of the appropriateness, quality and necessity of health care services and resources provided, or considered for providing, to members of a managed health care plan. Problems associated with utilization review, resulting in, for example, the denial of coverage for a medical procedure, has given rise to public concern, reflected by anecdotal complaints.

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<u>Item 4: The Process by which Less Burdensome and Intrusive Alternatives have been Considred.</u>

Promulgation of the regulations is the only means available for the Board to comply with the clear directive of SB 712 that the Board promulgate regulations to govern the quality of health care provided by MCHIPs. *See* Section 32.1-137.3 of the *Code*. This legislation responds to palpable public concerns over the emerging managed care environment. The experience in Virginia heretofore has not included a regulatory program designed to assure quality. This alternative has proven inadequate and has demonstrated that there are no less burdensome or intrusive alternatives that protect public health other than implementing a sound and effective regulatory program that will address legitimate public concerns.

<u>Item 5: Assessing the Impact of the Contemplated Regulation on the Family.</u>

The contemplated regulations will have a direct benefit for families in Virginia whose members are enrolled in MCHIPs by helping to assure the quality of these plans, and thereby, the medical care they receive. A particular benefit for families will result from developing an avenue for the redress of complaints against MCHIP licensees. These regulations will also have an indirect benefit on nearly all Virginians, by creating protections that will assure the quality of and lend credibility and stability to the emerging managed health care environment.