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December 5, 2005

Mr. John R. McGinley, Jr., Esq.
Chairman
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Re: State Board of Medicine Proposed Rulemaking for Physician Assistants (35 Pa.B. 6127)

Dear Chairman McGinley:

On behalf of our nearly 4.1 million health insurance subscribers, Highmark welcomes the opportunity to provide comments on the State Board of Medicine's proposed regulations for physician assistants (PAs).

Highmark appreciates the State Board of Medicine's (the Board) efforts to revise the regulations governing practice standards for physician assistants. Highmark commends the Board for its efforts to amend the existing PA regulations to reflect the current state-of-the-art medical practice, given the significant changes in standards of care that have evolved since the regulations were last updated. In particular, Highmark appreciates the Board's efforts to revise the regulations in such a manner that affords increased flexibility for physicians and health care facilities in appropriately utilizing PAs, as well as reduced regulatory burdens that do not contribute to the provision of safe quality care. Highmark fully supports public accountability for the services delivered by PAs in conjunction with physicians, and recognizes that the Board must balance the interests of the provider community with its primary goal, which is to develop standards that safeguard patients.

Physician assistants, delivering care in partnership with physicians, serve vital roles in the state's health care delivery system. PAs have improved access to health care services and improved the delivery of care for the citizens of Pennsylvania, especially in rural, inner city, and other medically underserved areas. To a very large extent, the proposed revisions to the regulations governing PA practice reflect the current standards for medical practice and will allow for the effective use of PAs to the full extent of their training. However, there are some changes to the regulations that Highmark questions as being in the best interest of patient safety and quality.

To a very large extent, PA scope of practice is determined by the delegatory decision made by the supervising physician. This allows for flexible and customized team deployment. The physician has the ability to observe the PA's competency and performance and to assure that the PA is performing tasks and procedures in the manner

preferred by the supervising physician. The physician is also in the best position to assess the acuity of patient problems seen in a particular setting. The supervising physician is able to plan for PA utilization in a manner that is consistent with the PA's abilities, the physician's delegatory style, and the needs of the patients seen in the practice. While Highmark supports changes to the current regulations that eliminate cumbersome and ineffective requirements governing this relationship, the following are current requirements that have been eliminated that Highmark would recommend be retained:

- Current Section 18.158(c)(4)(viii) prohibits a PA from issuing a prescription for more than a 30-day supply, except in cases of chronic illnesses. It allows PAs to authorize refills up to 6 months if the prescription is not otherwise precluded by law.

  There are very few chronic medical conditions that are appropriate for follow-up on an annual basis only. However, Highmark recognizes that there are maintenance medications that can be appropriately refilled annually, for example oral contraceptives during a well-visit. As a result, Highmark recommends that the current provision not be eliminated in its entirety, rather the provision should specify what medications can be refilled annually.

- The current regulations do not allow PAs to prescribe or dispense Schedule I or II controlled drugs. Proposed Section 18.158(a)(3) calls for allowing them to prescribe or dispense Scheduled II controlled drugs for initial therapy up to a 72-hour dose and requires that they notify the supervising physician within 24 hours. It would also allow the PA to write a prescription for a Schedule II controlled drug for up to a 30-day supply if originally ordered and approved for ongoing therapy by the supervising physician.

  Most of the medications in this class have the propensity for dependence and adverse effects, especially in certain patient populations such as the elderly. Highmark disagrees that the inability of PAs to write a prescription for a Schedule II narcotic impedes the care of patients, and recommends that the current provision be retained.

- Current Section 18.158(c)(4)(iii) does not allow PAs to prescribe medications for uses not approved by the FDA. This proposed rulemaking would no longer prohibit this "off-label" prescribing, but instead mandates that the PA follow the supervising physician's instructions and the written agreement.

  Highmark believes it is appropriate to follow the direction specified by the FDA for uses of medications. As a result, Highmark recommends that the current provision be retained.

- Current Section 18.158(a)(4) calls for new drugs and news uses for drugs to be approved for prescribing and dispensing purposes by PAs 90 days after approval by the FDA. This provision is being eliminated in the proposed rulemaking.

  There have been several examples of medications removed from the market for adverse affects immediately after introduction. For example, Tysabri, a medication for multiple sclerosis, was recently removed from the market shortly after its release due to concerns of increased cancer risk. This trend is likely to continue with the rush to market by the FDA of some medications. As a result, Highmark recommends that the current provision be retained.

Highmark recommends that language be added to the regulations that emphasize the need and requirement for effective and continuing communication between physicians and PAs who practice together, particularly in situations where there is a sudden change in the patient's condition. This requirement could be added to Section 18.142 (Written agreements) and/or Section 18.153 (Executing and relaying medical regimens).

There are changes to the regulations that ease the need for the physical presence and intervention of the physician in oversight of the PA, specifically changes that would no longer require constant physical presence of the supervising physician so long as the supervising physician and PA are or can easily be in contact with one another by radio, telephone or other telecommunication device. Given this loosening in the level of supervision, Highmark believes that in order to assure patient safety and quality care, an integral requirement for appropriate supervision are specific protocols for PAs to follow to contact the supervising physician in situations that involve sudden changes in the patient's condition, in emergency or urgent situations, and in situations where a physician supervises more than one PA, contingency plans for assuring necessary "on-call" supervisory availability/access. Having these protocols in place will allow the PA to exercise his or her clinical judgment while ensuring that the supervising physician is consulted in appropriate situations. Even with the addition of these protocols to the regulations, private payors may today and in the future have stricter medical policies and guidelines regarding scope of practice, supervision, and other practice issues in order to safeguard patient safety and assure quality care is provided to its members.

Finally, Highmark recommends that language be added to the regulations that require the supervising physician to assess the PA's abilities, knowledge and skills on an on-going basis. Supervising physicians are ultimately responsible for their assistant's work and must ensure regular oversight of their clinical competence. Enabling legislation empowers PAs to perform any clinical task within their scope of practice and sanctioned by their supervising physicians. However, this does not mean that every PA is qualified to provide every service, even though they may be able to do so "legally." The PA's supervising physician must be held accountable as the best judge of individual PAs' knowledge and skills. The regulations should reflect this responsibility.

Highmark is committed to working with the State Board of Medicine and Independent Regulatory Review Commission in improving the regulations governing the practice of physician assistants and assuring patient safety and quality of care. I appreciate the opportunity to present Highmark's recommendations on the proposed rulemaking.

If you would like to discuss any of these comments, please contact me at (717) 302-3982 or via email at candy.gallaher@highmark.com.

Sincerely,

Colleen M. (Candy) Gallaher
Director, Regulatory Affairs

c: Lisa M. Boscola, Minority Chair, Senate Consumer Protection and Professional Licensure Committee
Thomas P. Gannon, Majority Chair, House Professional Licensure Committee
Charles D. Hummer, Jr., M.D., Chairman, State Board of Medicine
John H. Jewett, Regulatory Analyst, Independent Regulatory Review Commission
William W. Rieger, Minority Chair, House Professional Licensure Committee
Gerald S. Smith, Board Counsel, State Board of Medicine
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