Economic Impact Analysis
Virginia Department of Planning and Budget

18 VAC 85-50 – Regulations Governing the Practice of Physician Assistants
Department of Health Professions
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Summary of the Proposed Amendments to Regulation

The Board of Medicine (Board) proposes to amend its Regulations Governing the Practice of Physician Assistants to include new regulatory guidelines for pain management. These proposed rules separately address the treatment of acute pain and the management of chronic pain.

Result of Analysis

There is insufficient information to accurately gauge whether benefits will outweigh costs for this proposed regulatory action. Benefits and costs are discussed below.

Estimated Economic Impact

Currently, there are no regulations in place for treatment of acute pain, defined as "pain that occurs within the normal course of a disease or condition or as the result of surgery for which controlled substances may be prescribed for no more than six months". Nor are there regulations to set rules for management of chronic pain, which is defined by the Board as "nonmalignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period of greater than six months". In 2004, the Board did adopt guidelines for the treatment of chronic pain (The Federation of State Medical Boards of the United States' *Model Policy for the Use of Controlled Substances for the Treatment of Pain*). These guidelines address the management of chronic pain and, to a lesser extent, the treatment of acute pain, but do not have the force of law. Because of this, the Board cannot hold regulated entities responsible for following these guidelines and regulated entities

must work in an environment of greater uncertainty than if the rules for such pain treatment were promulgated into law.

The Board seeks to amend its Regulations Governing the Practice of Physician Assistants to include new regulatory language for both the treatment of acute pain and the management of chronic pain. The Board believes that this regulatory change will give it a tool to enforce good pain management practices among its licensees and might lower the probability that drugs that are prescribed by licensees are abused or diverted. The Board also hopes that having rules in place will help ease uncertainty and encourage Board licensees who have the legal authority to prescribe medication (prescribers) to treat more pain patients in a way that provides them adequate relief.

The proposed regulations impose only minimal requirements for the treatment of acute pain. Prescribers will be required to get a history from their patients and will have to perform an examination that is appropriate for the complaint. After treatment commences, prescribers will have to keep medical records that include all diagnostic information, a treatment plan and detailed information for any medication they prescribe. As these requirements are likely already common medical practice, licensees are unlikely to incur any costs on account of the portion of the proposed regulations that covers the treatment of acute pain. To the extent that any licensees were not already keeping complete records on their patients, this portion of the proposed regulations will provide the small benefit of additional clarity as to what is expected.

The portion of the proposed regulations that set rules for the management of chronic pain will require prescribers, before treating a patient, to obtain a medical history and perform a physical examination. These proposed rules will also require prescribers to have a treatment plan which includes notes for any diagnostic tests run, notes or referrals for other treatments or therapies that might occur and notes that describe the presence or absence of any indicators of medication misuse, abuse or diversion. Prescribers will also be required to obtain “informed consent and (a written) agreement for treatment” from each of their patients. The written agreement will include, among other things, signed permission for the prescriber to query the prescription monitoring program. If a patient is deemed to be at high risk for medication abuse, or already has a history of substance abuse, the proposed regulations recommend that prescribers

also consider obtaining written agreement that the patient will submit to urine and/or blood drug tests when such tests are requested by the prescriber.

It must be noted, before any analysis of the costs and benefits of the proposed rules for chronic pain management, that there are almost no empirical studies that measure the effects of increased regulation on pain management practices. On the other hand, there are a wealth of available published surveys and anecdotes. Numbers for the Department of Planning and Budget's (DPB's) analysis are drawn from disparate sources and, therefore, must be read with the caveat that information used was not all generated at the same point in time. For instance, (very rough) estimates for the economic costs of drug abuse are drawn from a 2001 report issued by the Office of National Drug Abuse Policy (revised estimated costs for 1998 are used in this analysis). Estimates of the economic costs of untreated pain are drawn from a paper published in 2006 which, in turn, draws its numbers from 1995 estimates issued by the American Pain Society. It must also be noted that this analysis represents a static picture of a dynamic medical field which is greatly impacted by other than medical considerations. David Brushwood notes (2003, p. 46), when writing about prescription monitoring programs, that "although (these programs) are developed and administered by highly motivated people who genuinely wish no pain patient to be deprived of necessary pain medication, they cannot change the background against which the program operates". These proposed regulatory changes cannot usefully be analyzed without accounting for current trends in drug-related law enforcement, particularly by the federal government.

The Board proposes to require all chronic pain patients to sign a permission form that allows prescribers to query the state's prescription monitoring program (PMP). As this program is currently funded by a $20 million endowment, neither prescribers nor patients nor Virginia's taxpayers must pay directly for PMP queries. This requirement is, however, likely to increase the number of queries of this database and, so, will likely increase costs that are paid through the endowment and will likely exhaust those funds more quickly. To the extent that utilization of the PMP lowers the volume of drugs diverted from licit to illicit uses, this requirement will provide the benefit of reductions in the costs of illicit drug use in the state. Opioid drugs do, however, make their way to the streets through other routes besides through monitored prescriptions, including robberies of drug manufacturers, drug wholesalers or pharmacies and sales over the internet. Because of this, any benefit from decreasing the supply of diverted prescriptions is

likely to be mitigated by likely increases in opioids coming from these other routes. Indirect costs and benefits are, obviously, harder to measure. To the extent that prescribers and patients feel this requirement is only minimally invasive and worthwhile, both these groups may benefit from the trust that might be built because of repeated "clean" queries. To the extent that this requirement sets up or exacerbates an adversarial relationship between prescribers and their patients, indirect costs may accrue. These indirect costs might include, among other things, increasing costs for untreated pain if patients are actually driven away from seeking treatment for their pain. These indirect costs, however, are less likely to be realized on account of queries to the PMP than they would be on account of drug testing. In any case, both costs and benefits for this requirement are likely small and benefits likely outweigh costs.

For chronic pain patients deemed to be at high risk for medication abuse, or who already have a history of substance abuse, the proposed regulations recommend that prescribers also consider obtaining written agreement that the patient will submit to urine and/or blood drug tests when such tests are requested by the prescriber. The Board reports that they are proposing this in the hopes that it will help reduce the level of drug abuse by chronic pain patients and the level of drug diversion by individuals who may or may not be legitimate pain patients. Drug abuse, and diversion of drugs that might exacerbate that abuse, are undoubtedly an expensive burden that is borne by drug abusers and their families as well as by society as a whole.

Numbers parsed from a 2001 report issued by the Office of National Drug Control Policy indicate that Virginia's share of the approximate economic costs of drug abuse for 1998 would be $1.3 billion.[1] This estimate includes most costs for healthcare and loss of productivity, including costs for premature death (see footnote 1), but does not include law enforcement costs. Law enforcement costs are not included for two reasons; 1) law enforcement costs are more a function of policy decisions at the state and national level than they are a function of the health issues under discussion and 2) the numbers that are available for the costs of untreated pain do not appear to include law enforcement costs; so leaving those costs out here would make those numbers more directly analogous. No estimates were available for the cost that is attributable to prescription drug abuse so it impossible to say precisely how much of that $1.3 billion cost was

[1] Since the dollar amount tallied in the 2001 paper includes all costs for drug abuse, and this analysis is trying to ascertain just the costs associated with prescription drug abuse, any costs that were clearly unrelated to prescription drug abuse (like the costs for HIV/AIDS treatment) were not considered.

caused by the opioids that are the subject of these regulations. It is safe to say, however, that prescription abuse cost less than $1.3 billion in 1998 and likely cost much less. To the extent that this proposed regulatory change reduces the costs that Virginia incurs on an annual basis on account of drug abuse, and to the extent that it increases the number of drug addicts who are directed to appropriate treatment, this regulatory change will provide a benefit for the Commonwealth. That benefit must, however, be weighed against the direct and indirect costs of drug testing.

The Board reports based on national estimates, that 30% of Virginians may be candidates for pain management treatment. Ronald Libby (2006, p. 514) reports that "only one in four pain patients received treatment adequate to relieve suffering". Since there are no good estimates of the number of individuals who actually receive chronic pain treatment in Virginia annually, Board and Libby estimates will be used to create an upper and lower bound of probable patients. The population of Virginia, according to 2006 census figures, is 7,642,884. Thirty percent of this number, 2,292,865, can serve as the upper bound for the possible number of chronic pain patients in Virginia. This number * .25 (the likely percent of pain patients receiving adequate treatment), or 573,216, can serve as a probable lower bound for the number of possible pain patients.

It is impossible to say how many of these patients will be judged by their prescribers to be at high risk for medication abuse. Representatives of the Board, however, estimate that 15%-20% of patients misuse or abuse drugs and that another 2%-3% divert drugs. Dr. Martha Wunsch, an expert in addiction medicine and pediatric psychiatry, reports that addiction patterns in pain management patients likely approximate patterns in the general population. That is, on average, 10%-12% of this population will be vulnerable to addiction. While the exact number of individuals who may be subject to testing is unknown, DPB was able to obtain information on what these tests will likely cost.

Dr. Wunsch reports that initial urine testing costs between $6-$20, depending on the substances that will be tested for. She also reports that more sophisticated follow-up gas chromatography/mass spectrometry (gc/ms) tests cost between $125-$250. Individuals who "fail" initial urine tests by testing positive for unexpected drugs will have to undergo expensive

gc/ms testing. If prescribers attempt to use drug testing to weed out drug diverters, individuals who test negative for expected drugs may also have to undergo the more expensive testing. Some percentage of individuals who test positive for unexpected drugs, or who test negative for expected drugs, will have gc/ms test results that do not match initial urine test results. This is because initial tests have a false positive rate that can range from relatively small to moderate and a false negative rate that is likely quite large.

One source (Pollack, et al, 2001) reports a false positive rate (the rate of tests that are positive when none of the tested for "bad" drugs are actually present) of 7% for simple urine tests. Another source (Levy, et al, 2007) calculated a false positive rate of 21% for drug tests given within a study of adolescents under treatment for drug abuse. The rate of false negatives (the rate of initial tests that that are negative for expected drugs when those drugs are actually present) appears to be, on average, much higher than the rate of false positives. The Levy study, for instance, calculated a false negative rate (on tests for opiates) of 62%. Another paper (Gleason and Barnum, 1991) summarizes two studies published by the Journal of the American Medical Association (JAMA) and reports false negative rates (for those studies) of 31% and 62%.

If prescribers use drug testing of high-risk individuals strictly as a tool for identifying drug abusers who might benefit from referral for addiction treatment, it is likely that 7% to 20% of individuals identified by initial tests will be exonerated by subsequent testing. If prescribers also attempt to use drug testing to weed out patients who may be diverting drugs, 30% to 60% of individuals who initially test negative for expected drugs, and who subsequently have gc/ms testing, will have those initial test results disproved. Because there is a much higher rate of false negative results in initial drug testing, using these tests for anything but identifying drug abusers is likely an inefficient use of resources. PMP queries are likely a more efficient means of identifying drug diverters.

None of the sources contacted during research for this analysis were sure if patient health insurance would cover the cost of drug testing. Patients will likely have to bear, directly and immediately, the costs of both initial and subsequent drug tests. To the extent that drug testing sets up or exacerbates an adversarial relationship between prescribers and patients, indirect costs may accrue. These indirect costs may include increasing suspicion and decreasing

communication between prescribers and patients; both of which might adversely impact patient outcomes. Indirect costs might also include increasing costs for untreated pain if patients are actually driven away from seeking treatment for their pain either because they do not wish to undergo drug testing at all or because they are abusing drugs and expect that drug testing will cause them to lose access to treatment for their pain anyway.

Not treating individuals who are actually in pain has enormous costs. The national annual cost of untreated pain was estimated, in 1995, to be $100 billion dollars. (Libby, 2006: Brushwood, 2003). This estimate included "medical expenses, lost wages and other costs, including 50 million (lost) workdays". (Libby, 2006) Virginia's proportional share of these 1995 costs would have been $2.5 billion. Although there is no information that indicates the cost of untreated pain in 2006, DPB has found no source that indicates that it would be significantly lower than the 1995 numbers. Whether these proposed regulations benefit citizens of the Commonwealth more than they cost will likely depend on whether any reduction in the annual costs of drug abuse is greater in magnitude than the direct costs of drug testing plus any increase in the annual costs of untreated pain (that is attributable to this regulatory change).

Businesses and Entities Affected

The Board currently licenses 1,540 physician assistants; all of whom will be affected by these proposed regulatory changes.

Localities Particularly Affected

No locality will be particularly affected by this proposed regulatory action.

Projected Impact on Employment

If these proposed regulatory changes lead to fewer individuals being treated for chronic pain, employee absenteeism may increase. This effect would tend to depress total productivity in the Commonwealth. If, on the other hand, these changes allow more effective treatment of drug addicts, absenteeism that is part of the cost of drug abuse may decrease. This effect would tend to increase total productivity in the Commonwealth.

Effects on the Use and Value of Private Property

To the extent that promulgating regulations for pain management eases law enforcement pressures on the medical community, these proposed regulation may lower the risk of law enforcement seizing prescribers' property.

Small Businesses: Costs and Other Effects

The Department of Health Professions (DHP) reports that it is not known how many doctors practice independently, or in small groups that would qualify as small businesses, and also employ physician assistants. These individuals (and groups) are unlikely to experience any increase in bookkeeping costs on account of these regulatory changes.

Small Businesses: Alternative Method that Minimizes Adverse Impact

There is likely no alternative regulatory proposal that would both accomplish the Board's goals and further minimize any adverse impact for affected small businesses.

Real Estate Development Costs

This regulatory action will likely have no affect on real estate development costs in the Commonwealth.

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Legal Mandate

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.H of the Administrative Process Act and Executive Order Number 36 (06). Section 2.2-4007.H requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, Section 2.2-4007.H requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the

type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.