Economic Impact Analysis
Virginia Department of Planning and Budget

18 VAC 85-20 – Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic
Department of Health Professions
November 23, 2007

Summary of the Proposed Amendments to Regulation

The Board of Medicine (Board) proposes to amend its Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic 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

The costs likely exceed the benefits for these proposed regulatory changes.

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 Medicine, Osteopathic Medicine, Podiatry and Chiropractic 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 them 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 doctors 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. Doctors 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, doctors 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 doctors, before treating a patient, to obtain a medical history and perform a physical examination which must include a urine drug screen. These proposed rules will also require doctors 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. Doctors 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, 1) signed permission for the doctor to query the prescription monitoring program and 2) agreement to submit to further urine and/or blood drug tests when such tests are requested by the doctor.

Although the Board relied heavily on its adopted guidance document for pain management when writing these proposed regulations, neither of these two enumerated parts of the proposed required written agreements originated in that document. It seems likely that the national model policy fails to address the appropriate usage of prescription monitoring programs

because not all states have prescription monitoring programs. The national model policy suggests a written agreement for urine/blood drug screens only for patients "at high risk for medication abuse or (who have) a history of substance abuse". The proposed regulation will require such drug tests for all chronic pain patients. A representative of the Board reports that this requirement was added to the proposed regulations at the suggestion of several doctors who specialize in drug abuse treatment. This requirement is also present in the Board's guidance policy for treatment of substance abuse in doctors' offices.

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 is a wealth of anecdotal evidence and published surveys. 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 doctors to query the state's prescription monitoring program (PMP). As this program is currently funded by a $20 million endowment, neither doctors 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 lower 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 doctors 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 doctors 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 enforced drug testing. In any case, both costs and benefits for this requirement are likely small and benefits likely outweigh the costs.

The Board also proposes to require all chronic pain patients to undergo a urine drug screen before they can start treatment for chronic pain and to sign an agreement that allows their doctor to ask for other urine/blood drug screens during the course of ongoing treatments. The Board reports that they are proposing this requirement 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 **ALL** 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

[1] Since this figure includes all costs for all 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.

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 of the proportion of total drug abuse that is attributable to prescription drug abuse so it is impossible to say precisely how much of that $1.3 billion cost was caused by the opioids that are the subject of this regulation. 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, this regulatory change will provide a benefit for the Commonwealth. That benefit is however, likely to be swamped by the direct annual costs of drug testing and the annual costs of untreated pain for citizens of Virginia.

The direct annual cost of drug testing all chronic pain patients will likely be very large. The Board reports, based on national estimates, 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.[2]

Dr Martha Wunsch, an expert in addiction medicine and pediatrics psychiatry, reports that initial urine tests will cost between $6 and $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 and $250. Individuals who "fail" initial urine tests, either by testing positive for unexpected drugs or testing negative for expected drugs, will have to undergo the more expensive testing.

Web research (Pollack, et al, 2001) yields 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. The rate of false negatives (the rate of 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

[2] The population of Virginia, according to 2006 census figures, is 7,642, 884. 30% of this number, 2,292,865, will serve as the upper bound for the possible number of patients that would be affected by this proposed regulatory requirement. This number * .25 (the likely percent of pain patients receiving adequate treatment), or 573,216, will serve as the lower bound for the number of possible pain patients.

positives but for expediency's sake we will allow the rate of false negatives to exactly mimic the rate of false positives. Assuming perfect behavior in pain patients, meaning none of these patients are abusing or diverting drugs, 14% of those who take initial urine tests will be referred for the higher cost test. Assuming perfect behavior for pain patients, at the lower bound pretreatment drug testing will cost, on average, $22.5 million (range: $13.5 million to $31.5 million).[3] At the upper bound, pre-treatment drug testing will cost, on average, $90 million (range: $53.9 million to $126.1 million). This does not account for law enforcement (Kaufman, 2003: Tierney, 2007) and regulatory pressures that are likely to encourage doctors to practice frequent defensive testing. Assumptions of quarterly testing (since doctors are able to write prescriptions for three months worth of medication at one visit) drive the annual direct cost of drug testing up to an average of $112.5 million to $450 million. None of the sources contacted during research for this analysis were sure if patient health insurance would cover the cost of this drug testing. These costs might have to be borne, directly and immediately, by pain patients.

The above cost of testing assumes perfect patient behavior. We know, however, that the population of pain patients does not behave perfectly. Representatives of the Board estimate that 15%-20% of patients misuse or abuse drugs and that another 2%-3% are diverting drugs. Dr. Wunsch 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. Individuals who test positive for drugs that would lead to denial of pain treatment, and for whom that test result is correct, would likely be less willing to agree to follow up tests, would be less likely to be part of the pool of individuals who are subject to continuing drug testing and would be less likely to receive treatment even when they are actually experiencing chronic pain and would benefit from treatment. Although the Board hopes that these proposed regulations will lead to a greater number of individuals in chronic pain receiving treatment, this result would seem to run contrary to the incentives (for doctors and patients) that the proposed changes set up. It seems that the proposal for drug testing, in particular, makes it more likely that a greater

[3] Average lower bound cost is calculated by taking the mean of the costs for initial urine testing quoted by Dr. Wunsch ((6+20)/2=13) and multiplying it by the lower bound number for affected patients (573,216). The range is calculated by multiplying 6 and 20, respectively, by 573,216. Analogously, average upper bound cost estimates are gotten by multiplying the mean cost of the gc/ms test (187.50) by 30% of the Commonwealth's population.

number of pain treatment candidates would not receive treatment. 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. In any case, assuming that a portion of the individuals who would likely have a true positive result for urine drug testing are actually suffering from chronic pain and would not receive treatment because of that true positive result, the proposed drug testing will likely drive up the annual cost to Virginians of untreated pain.

Businesses and Entities Affected

The Board currently licenses 26,982 active doctors of medicine, 816 active doctors of osteopathic medicine and 414 active doctors of podiatric medicine. All of these licensees 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

To the extent that these proposed regulatory changes lead to fewer individuals being treated for chronic pain, employee absenteeism may increase. This would depress 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 doctors’ 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. These

individuals (and groups) will likely experience higher book keeping costs associated with increased record and testing requirements for chronic pain patients because of the proposed regulation.

Small Businesses: Alternative Method that Minimizes Adverse Impact

Costs for small business doctors and their patients alike would likely be lowered if the Board revisits and modifies the requirement for drug testing in the proposed regulations.

Real Estate Development Costs

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

References

Brody, Jane E. 2007. Living With Pain That Just Won't Go Away. *The New York Times*, January 6.

Brushwood, David B. 2003. Maximizing the Value of Electronic Prescription Monitoring Programs. *Journal of Law, Medicine & Ethics*, 31: 41-54.

Joranson, David E., Aaron Gilson. 2001. Pharmacists' Knowledge of and Attitudes Toward Opioid Pain Medications in Relation to Federal and State Policies. *Journal of the American Pharmaceutical Association*, 41: 213-220.

Kaufman, Marc. 2003. Worried Pain Doctors Decry Prosecutions. *Washington Post*, December 29.

Libby, Ronald. 2006. Treating Doctors as Drug Dealers: The Drug Enforcement Administration's War on Prescription Painkillers. *The Independent Review*, v.X, no.4:513-547.

Pollack, Harold, Sheldon Danzinger, Rukmalie Jayakody, Kristen Seefeldt. 2001. Drug Testing Welfare Recipients – False Positives, False Negatives, Unanticipated Opportunities.

Office of National Drug Control Policy. 2001. *The Economic Costs of Drug Abuse in the United*

States 1992-1998.Washington D.C.: Executive Office of the President. Publication No. NCJ-190636.

Tierney, John. 2007. Trafficker or Healer? And Who's the Victim?. *The New York Times*, March 23.

Tierney, John. 2007. Juggling Figures, and Justice, in a Doctor's Trial. *The New York Times*, July 3.

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.