Senate Fiscal Agency
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BILL ANALYSIS

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Senate Bill 789 (as enacted) **PUBLIC ACT 182 of 2012**
House Bills 5338 and 5714 (as enacted) **PUBLIC ACTS 180 & 181 of 2012**
Sponsor: Senator Rick Jones (S.B. 789)
Representative Edward McBroom (H.B. 5338)
Representative Pat Somerville (H.B. 5714)
Senate Committee: Judiciary (S.B. 789 & H.B. 5338)
House Committee: Judiciary

Date Completed: 9-19-12

RATIONALE

The Public Health Code includes five separate schedules of controlled substances and prescribes criminal penalties for the improper manufacture, delivery, possession, and use of those substances. Often, however, illicit drug producers have eluded criminal liability by manufacturing and marketing so-called designer drugs that differ only slightly from scheduled controlled substances. Although individual substances may be added to the various schedules either by statutory amendment or administrative procedures, neither process allows additional items to be scheduled expeditiously. It was suggested that the law should permit more flexibility in adding controlled substances to the schedules, by authorizing the Michigan Board of Pharmacy to schedule a controlled substance by emergency rule at the request of the Director of the Department of Community Health (DCH).

In addition, Federal law contains similar schedules of controlled substances, and the Code previously provided for the inclusion of federally scheduled substances in Michigan's schedules if the Board of Pharmacy held a meeting within 91 days of receiving a Federal notice, to determine whether a substance should be controlled under Michigan law. Some people recommended that federally scheduled substances be included automatically in Michigan's schedules *unless* the Board holds such a meeting.

CONTENT

House Bill 5338 and Senate Bill 789 amended the Public Health Code to do the following:

-- Require the DCH Director to notify the Director of the Department of Licensing and Regulatory Affairs (LARA) and the Michigan Board of Pharmacy if the DCH Director determines that imminent danger to life or health can be prevented or controlled by scheduling a substance as a controlled substance by emergency rule.
-- Allow the Board of Pharmacy to pursue the scheduling or rescheduling of a substance by emergency rule after a notification by the DCH Director of a substance's imminent danger.
-- Revise the procedure for State scheduling of a federally scheduled substance.
-- Specify that an "imitation controlled substance" does not include a placebo or registered investigational drug.
-- Identify factors to be considered in determining whether a substance is an imitation controlled substance.

House Bill 5714 amended the Administrative Procedures Act to establish procedures for the adoption of an emergency rule scheduling a substance as a controlled substance, without a hearing, if the DCH Director

determines that scheduling the substance can prevent or control an imminent danger to the health or lives of people in Michigan.

All of the bills were tie-barred and took effect on June 19, 2012.

House Bill 5338

Imminent Danger/Emergency Rule

Under the bill, if the DCH Director determines that an imminent danger to the health or lives of individuals in Michigan may be prevented or controlled by the promulgation of an emergency rule under the Administrative Procedures Act (as amended by House Bill 5714) to schedule or reschedule a substance as a controlled substance, the DCH Director must notify the LARA Director and the Michigan Board of Pharmacy (the "administrator"). The notification must be in writing and include a description of the substance and the grounds for the DCH Director's determination. The Director may provide copies of police, hospital, and laboratory reports and other information as he or she considers appropriate.

(Under the Public Health Code, "imminent danger" means a condition or practice exists that could reasonably be expected to cause death, disease, or serious physical harm immediately or before the imminence of the danger can be eliminated through enforcement procedures otherwise provided.)

Imitation Controlled Substance

Except as otherwise provided in the Code for purposes of placebos in legitimate medical, therapeutic, or research purposes, a person may not manufacture, distribute, possess with intent to distribute, or use an imitation controlled substance.

"Imitation controlled substance" means a substance that is not a controlled substance or is not a drug for which prescription is required under Federal or State law, which by dosage unit appearance including color, shape, size, or markings, and/or by representations made, would lead a reasonable person to believe that the substance is a controlled substance. This does not apply to a drug that is not a controlled substance if it was marketed before the controlled substance that it physically resembles.

The bill specifies that an imitation controlled substance does not include a placebo or registered investigational drug that was manufactured, distributed, possessed, or delivered in the ordinary course of professional practice or research. All of the following factors must be considered in determining whether a substance is an imitation controlled substance:

-- Whether the substance was approved by the U.S. Food and Drug Administration (FDA) for over-the-counter sales and was sold in the FDA-approved packaging and labeling information.
-- Any statements made by an owner or another person in control of the substance concerning its nature, use, or effect.
-- Whether the substance was packaged in a manner normally used for illicit controlled substances.
-- Whether the owner or another person in control of the substance has any prior convictions related to controlled substances or fraud.
-- The proximity of the substance to controlled substances.
-- Whether the consideration tendered in exchange for the substance substantially exceeds the reasonable value of the substance, considering its actual chemical composition and, if applicable, the price of over-the counter substances of like chemical composition.

Senate Bill 789

Scheduling of Substance

The Public Health Code requires the Board of Pharmacy to administer Article 7 (Controlled Substances) of the Code, and allows it to add substances to, or delete or reschedule substances in, the schedules enumerated in Article 7 pursuant to the Administrative Procedures Act (APA). In making a determination regarding a substance, the Board must consider all of the following:

-- The actual or relative potential for abuse.
-- The scientific evidence of its pharmacological effect, if known.

-- The state of current scientific knowledge regarding the substance.
-- The history and current pattern of abuse.
-- The scope, duration, and significance of abuse.
-- The risk to the public health.
-- The potential of the substance to produce psychic or physiological dependence liability.
-- Whether the substance is an immediate precursor of a substance already controlled under Article 7.

The bill added a requirement that, in making a determination regarding a substance that is the subject of an emergency rule, the Board also consider whether the DCH Director has notified the Board that the substance constitutes an imminent danger as defined in Section 2251 (a section House Bill 5338 amended).

The Code requires the Board, after considering the factors listed above, to make findings with respect to the factors and promulgate a rule controlling the substance, if the Board finds the substance has a potential for abuse. Under the bill, if the DCH Director notifies the Board that a substance constitutes an imminent danger, after considering the factors and making findings about them, the Board may do either or both of the following:

-- Proceed under the APA (as amended by House Bill 5714) to schedule or reschedule the substance as a controlled substance by emergency rule.
-- Initiate and pursue the process to promulgate a rule controlling the substance.

The Board may extend an emergency rule by filing a certificate of extension with the Secretary of State before the emergency rule expires (as provided in the House Bill 5714).

State Scheduling of Federal Schedule

Previously, under the Code, if a substance was designated, rescheduled, or deleted as a controlled substance under Federal law and notice of that action was given to the Board of Pharmacy, the Board was required hold a meeting within 91 days to determine whether the substance should be similarly controlled under State law. Under the bill, instead, if the Board receives such a notice, the substance must be similarly scheduled under State law unless the Board holds a meeting within 91 days to determine whether the substance should be controlled under State law.

House Bill 5714

Under the bill, if the DCH Director determines that an imminent danger to the health or lives of individuals in Michigan can be prevented or controlled by scheduling a substance as a controlled substance under the Public Health Code, and the Board of Pharmacy determines that the substance should be scheduled or rescheduled as a controlled substance, LARA may dispense with all or part of the procedures required under Sections 41 and 42 of the APA, and file with the Secretary of State copies as required by the Act endorsed as an emergency rule. (Sections 41 and 42 contain public hearing, notice, and publication requirements that must be met before a rule is adopted.) The Office of Regulatory Reinvention (ORR) must submit the emergency rule draft language to the Legislative Service Bureau (LSB) for formal certification. If the LSB fails to issue a certificate of approval within seven business days after receiving the draft language, the ORR may issue a certificate of approval. Upon receipt from the LSB, the ORR must approve the rule within seven business days if the ORR considers the rule to be legal and appropriate.

An emergency rule adopted under these provisions will remain in effect until the earliest of the following:

-- An identical or similar rule is promulgated.
-- An identical or similar bill is enacted.
-- The Board of Pharmacy determines that the emergency rule is no longer necessary.
-- Six months after its filing.

The six-month period may be extended for up to six more months if the Board files a certificate of extension with the Secretary of State before the first period expires.

MCL 333.7201-333.7204 (S.B. 789)
333.2251 & 333.7341 (H.B. 5338)
24.248 (H.B. 5714)

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

The legislative process and administrative procedures for adding a substance to Michigan's controlled substance schedules can be cumbersome and time-consuming. Consequently, law enforcement and public health officials have had difficulty confronting the development of dangerous new designer drugs in a timely manner. Several pieces of legislation in recent years have addressed problems with synthetic cannabinoid compounds, known by names like "K2", "Spice", and "Spice Gold", and designer amphetamines widely known as "bath salts", and those substances have been added to Schedule 1. Those substances and similar chemical compounds, however, have been widely distributed and used, with dangerous consequences in some cases. Chemists sometimes develop similar compounds that mimic the effects of substances like synthetic marihuana and bath salts, without strictly meeting the chemical structure now listed in law as a controlled substance.

Rather than seeking an amendment to the Public Health Code every time a dangerous new designer-type drug surfaces in Michigan communities, law enforcement and public health officials need the ability to respond more rapidly. By authorizing the Michigan Board of Pharmacy to schedule a substance by emergency rule, the bills provide the flexibility needed to curb the distribution of newly developed compounds that can be hazardous and addictive. The Board's authority to place a substance in the schedules is not unilateral, however, and the scheduling of the substance will expire unless promulgated as a rule or added by statute. The Board may act only upon the recommendation of the DCH Director after he or she determines that an imminent danger to the health or lives of individuals can be prevented or controlled by the promulgation of an emergency rule. Scheduling a substance by emergency rule will allow immediate intervention into the distribution and use of a dangerous drug and provide the time needed to pursue the permanent addition of the substance to the schedules via legislation or administrative rule.

Supporting Argument

The Marquette County Health Officer submitted to the Senate Judiciary Committee written testimony about his response to problems associated with a particular type of amphetamine known as White Rush Bath Salts. Early in 2011, he was informed by the county's medical director and local law enforcement about a growing number of cases of individuals treated in local emergency rooms for problems associated with that new designer drug. The health officer was able to have an immediate effect on the sale of these bath salts through authority granted in Section 2451 of the Public Health Code, which allows a local health officer to make a determination that an imminent danger exists in the area he or she serves and to order immediate action to avoid, correct, or remove the danger. To have a regional affect in the Marquette area, though, two other neighboring health officers had to take similar action. By authorizing the DCH Director and the Board of Pharmacy to take similar actions with regard to harmful substances, the bills provide for statewide impact without the local process authorized by Section 2451 having to be repeated all across Michigan.

Supporting Argument

Senate Bill 789 will expedite the inclusion of federally scheduled substances in Michigan's controlled substance schedules. Previously, when substances were added to, rescheduled in, or deleted from the Federal schedules, the Board of Pharmacy had to hold a meeting within 91 days after receiving notice to determine whether the substance should be similarly controlled in Michigan. The bill essentially reverses that process by requiring a federally controlled substance to be included in Michigan's schedules *unless* a hearing is held within 91 days.

Legislative Analyst: Patrick Affholter

FISCAL IMPACT

Senate Bill 789 & House Bill 5338

The Michigan Board of Pharmacy will face minor administrative costs due to the

notification and public hearing components of the bills.

To the extent that the bills result in an increase in the number of criminal convictions related to controlled substances, the State and local units of government will incur additional correctional costs. Local governments incur the costs of incarceration in local facilities, which vary by county. The State incurs the cost of felony probation at an annual average cost of $2,500, as well as the cost of incarceration in a State facility at an average annual cost of $34,000. Additional penal fine revenue will benefit public libraries.

House Bill 5714

The bill will have an indeterminate, but likely slightly negative fiscal impact on the State's finances. The Department of Licensing and Regulatory Affairs and Department of Community Health will experience increased administrative costs associated with the issuance of emergency rules as authorized in the bill. These costs will likely be relatively small, as the costs associated with the promulgation of nonemergency rules include activities such as publishing notices for public hearings, holding public hearings, and producing various documents that explain the rules and their impacts. These activities and their associated costs will not apply to emergency rules, meaning personnel costs will be the only major expense associated with the emergency rules under the bill. The DCH, LARA, and the Legislative Service Bureau all will incur personnel costs for their respective responsibilities under the bill. It is not known at this time what the specific costs to each agency will be, but the costs will likely vary with the complexity of each emergency rule considered under the bill.

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