



ANALYSIS

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Senate Bill 857 (as enacted) House Bill 5404 (as enacted) House Bill 5405 (as enacted) House Bill 5407 (as enacted)

Sponsor: Senator Tonya Schuitmaker (S.B. 857)

Representative Hugh Crawford (H.B. 5404)

Representative Anthony G. Forlini (H.B. 5405 & 5407)

Senate Committee: Judiciary House Committee: Judiciary

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PUBLIC ACT 314 of 2014
PUBLIC ACT 312 of 2014
PUBLIC ACT 313 of 2014
PUBLIC ACT 311 of 2014

RATIONALE

Abuse of prescription drugs, particularly opioids, is a growing concern in Michigan and throughout the United States. According to the National Institute on Drug Abuse website, opioids are medications that reduce the intensity of pain signals reaching the brain and affect those areas of the brain that control emotion, thereby diminishing the effects of painful stimuli. When people become addicted to strong prescription painkillers—opioids—they may turn to illegal opiates such as heroin when their prescriptions run out. In recent years, abuse of both opioids and heroin, as well as the number of deaths from overdoses of both substances, has increased sharply, according to various reports and articles.

A substance that is an "opioid antagonist", however, can counteract the effects of overdose from either prescription drugs or heroin. In particular, a fast-acting medication called naloxone can be used to treat someone who is having, or is suspected of having, an overdose. Some people believe that the State should encourage the use of this medication, and promote its availability, by extending liability protection to people who administer or prescribe it, as well as requiring life support vehicles to carry the medication and requiring emergency personnel to be trained to administer it.

CONTENT

<u>Senate Bill 857</u> amended the Good Samaritan law to provide civil immunity for a person who administers an opioid antagonist to another individual under particular circumstances.

<u>House Bills 5404, 5405, and 5407</u> amended the Public Health Code relative to the use of an opioid antagonist in response to an opioid-related overdose.

House Bill 5404 does the following:

- -- Requires emergency medical protocols, within 12 months of the bill's effective date, to include requirements that life support vehicles have opioid antagonists and that emergency personnel are trained to administer them.
- -- Allows a medical control authority to rescind those protocols beginning three years after the bill's effective date.

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-- Grants liability protection to certain people for the administration of an opioid antagonist to someone who is suffering or exhibiting symptoms of an opioid-related overdose.

House Bill 5405 does the following:

- -- Specifies that a person complying with provisions authorizing an opioid antagonist to be prescribed and dispensed (provisions enacted by House Bill 5407) is not in violation of the Code's controlled substance prohibitions.
- -- Specifies that a person who in good faith administers an opioid antagonist to a person whom he or she believes is suffering from an opioid-related overdose is not subject to criminal prosecution or professional sanction.

House Bill 5407 does the following:

- -- Authorizes a prescriber to issue a prescription for, and a dispensing prescriber or pharmacist to dispense, an opioid antagonist.
- -- Grants civil liability protection to a prescriber, dispensing prescriber, or pharmacist who prescribes or dispenses an opioid antagonist that is administered or not administered, resulting in injury or death.
- -- Requires the Department of Community Health (DCH) to publish an annual report on opioid-related overdoses in Michigan.

Senate Bill 857 and House Bill 5407 define "opioid-related overdose" as a condition that results from the consumption or use of an opioid or another substance with which an opioid was combined or that a layperson would reasonably believe to be an opioid-related overdose that requires medical assistance. The conditions resulting from consumption or use of an opioid or other substance include, but are not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death.

The bills define "opioid antagonist" as naloxone hydrochloride or any other similarly acting and equally safe drug approved by the Federal Food and Drug Administration for the treatment of drug overdose.

All of the bills took effect on October 14, 2014.

Senate Bill 857

Under the bill, if a person in good faith believes that another person is suffering the immediate effects of an opioid-related overdose and administers an opioid antagonist to that person, the person who administers the opioid antagonist is not liable in a civil action for damages resulting from the administration of the opioid antagonist.

This liability protection does not apply in either of the following circumstances:

- -- The person who administers the opioid antagonist is a physician, physician's assistant, registered nurse, or licensed practical nurse and the opioid antagonist is administered in a hospital.
- -- The conduct of the individual administering the opioid antagonist is willful and wanton misconduct.

House Bill 5404

Emergency Medical Protocols

Part 209 (Emergency Medical Services) of the Code requires a medical control authority to establish written protocols for the practice of life support agencies and licensed emergency medical services personnel within its region. The authority must develop and adopt the protocols

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in accordance with procedures established by the DCH, in compliance with requirements specified in the Code.

Within 12 months after the bill's effective date, an authority must include protocols to ensure that each life support vehicle that is dispatched and responding to provide medical first response life support, basic life support, or limited advanced life support is equipped with opioid antagonists and that each emergency services personnel is properly trained to administer the opioid antagonists. Beginning three years after the bill's effective date, an authority, at its discretion, may rescind or continue the protocols adopted under the bill.

Liability Protection

Part 209 provides that, unless an act or omission is the result of gross negligence or willful misconduct, the acts or omissions of certain medical professionals do not impose liability in the treatment of a patient on those individuals or certain other people and entities. The liability protection applies to the use of an automated external defibrillator on an individual who is in or is exhibiting symptoms of cardiac distress. Under the bill, the liability protection also applies to the administration of an opioid antagonist to an individual who is suffering or exhibiting symptoms of an opioid-related overdose.

House Bill 5405

The bill specifies that a person complying with Section 17744b is not in violation of Article 7 (Controlled Substances) of the Public Health Code with regard to the prescribing, dispensing, possession, or administration of an opioid antagonist. (Section 17744b was enacted by House Bill 5407 and authorizes the prescribing and dispensing of an opioid antagonist under certain circumstances.)

The bill also would amended Part 177 (Pharmacy Practice and Drug Control) to specify that a person who administers an opioid antagonist to an individual whom he or she believes is suffering an opioid-related overdose, and who acts in good faith and with reasonable care, is immune from criminal prosecution or sanction under any professional licensing act for that action.

House Bill 5407

Prescribing & Dispensing Opioid Antagonists

The bill amended Part 177 to authorize a prescriber to issue a prescription for, and allow a dispensing prescriber or pharmacist to dispense, an opioid antagonist to an individual patient at risk of experiencing an opioid-related overdose; a family member, friend, or other individual in a position to assist a person at risk of experiencing an opioid-related overdose; or a person, other than an individual, that meets all of the following requirements:

- -- Acts at the direction of the prescriber or dispensing prescriber.
- -- Upon receiving an opioid antagonist, stores it in compliance with Part 177.
- -- Dispenses or administers an opioid antagonist under a valid prescription issued to an individual or a patient.
- -- Performs those requirements without charge or compensation.

When issuing a prescription for or dispensing an opioid antagonist to a person other than a patient, the prescriber, dispensing prescriber, or pharmacist must insert the name of the person as the name of the patient.

A person acting in good faith and with reasonable care may possess and dispense an opioid antagonist, notwithstanding any provisions of the Code to the contrary.

A prescriber who issues a prescription for, or a dispensing prescriber or pharmacist who dispenses, an opioid antagonist as authorized under the bill is not liable in a civil action for a

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properly stored and dispensed opioid antagonist that is a proximate cause of injury or death to an individual due to the administration of or failure to administer the opioid antagonist.

DCH Report

The bill requires the DCH, by February 1 of each year, to ascertain, document, and publish a report on the number, trends, patterns, and risk factors related to opioid-related overdose fatalities that occurred in Michigan in the preceding calendar year. The DCH must include in the report information on interventions that would be effective in reducing the rate of fatal or nonfatal opioid-related overdoses in Michigan.

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MCL 691.1503 (S.B. 857)
333.20919 & 333.20965 (H.B. 5404)
333.7422 & 333.17744c (H.B. 5405)
333.1106 et al. (H.B. 5407)
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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

According to a *USA Today* article that appeared in the *Detroit Free Press*, abuse of prescription opioids has fueled a surge in overdose deaths, which more than quadrupled from 4,030 in 1999 to almost 17,000 in 2011 before declining slightly in 2012 (*Detroit Free Press*, "Painkiller deaths drop, heroin deaths surge", 10-15-2014). The same article reported that people addicted to prescription narcotics may turn to heroin and that heroin use has risen sharply, resulting in an increase in heroin overdose fatalities from 4,397 in 2011 to 5,927 in 2012. In Michigan, the Department of Community Health has designated heroin as a "significant" public health problem, as heroin overdose deaths in the State increased from 271 in the four-year period of 1999-2002 to 728 in the three-year period of 2010, 2011, and 2012, and admissions to publicly funded heroin-treatment programs doubled from about 6,500 in 2002 to about 13,600 in 2013 (*Detroit Free Press*, "Heroin use, deaths in Michigan are on the rise", 4-5-2014).

Citing statistics from the Centers for Disease Control and Prevention, *State Legislatures* magazine, a publication of the National Conference of State Legislatures, reported that drug overdose has become the leading cause of injury death among people 25 to 64 years of age, surpassing motor vehicle crashes (*State Legislatures*, "Overdose Deaths Trigger State Action", April 2014). According to the article, pharmaceuticals, including prescription painkillers, were responsible for 60% of the drug overdose deaths in the United States in 2010, and almost half of the young people who inject heroin report having first abused prescription opioids.

The magnitude of the public health problem of opioid and heroin abuse demands policy changes to address the incidence of, and the death rate from, overdose. Making naloxone more readily available and providing liability protections for distributing and administering this opioid antagonist will save lives. According to a national advocacy organization called Harm Reduction Condition, naloxone is used in opioid overdoses to counteract life-threatening depression of the central nervous system and respiratory system, allowing an overdose victim to breathe normally; it is a nonscheduled, nonaddictive, prescription medication that works only if a person has opioids in his or her system; and it has no potential for abuse. While naloxone has long been administered by some emergency response personnel, it can be administered safely by virtually anyone, with minimal training. The opioid antagonist may be injected into muscle tissue or veins or under the skin, or be sprayed into the nose. Indeed, according to a Food and Drug Administration (FDA) news release dated April 3, 2014, the FDA has approved a prescription treatment of naloxone by a new hand-held auto-injection device that rapidly delivers a single dose of the drug.

By authorizing a prescriber to issue a prescription for naloxone, allowing a dispensing prescriber or pharmacist to dispense the drug or a similar opioid antagonist to a patient at risk of opioid

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overdose or someone else in a position to assist such a patient, and allowing a person acting in good faith and with reasonable care to possess and dispense an opioid antagonist, House Bill 5407 will make this fast-acting, life-saving medication more widely available to those who might need it. In addition, civil immunity under Senate Bill 857, House Bill 5404, and House Bill 5407, and criminal liability protections under House Bill 5405, will ensure that people in a position to prescribe, dispense, and administer an opioid antagonist in response to an opioid-related overdose are not deterred from doing so out of concern for civil liability, criminal responsibility, or professional sanction. This will encourage the use of opioid antagonists in emergency situations without fear of reprisal, resulting in saved lives.

Opposing Argument

Senate Bill 857 broadly expands the application of civil immunity under the Good Samaritan law. The law generally provides immunity from civil liability for certain medical professionals who offer medical aid in emergency situations, unless their acts or omissions amount to gross negligence or willful and wanton misconduct. The law is designed to encourage bystanders who are medical professionals to offer on-site care or assistance in an emergency situation without being exposed to a civil action claim by the people they attempt to assist. Senate Bill 857, however, extends civil liability protection under the Good Samaritan law to anyone (except a physician, physician's assistant, or nurse in a hospital) who administers an opioid antagonist to an individual whom he or she, in good faith, believes is suffering from an opioid-related overdose.

Response: The scope of the Good Samaritan law has long exceeded providing immunity to doctors and certain other medical professionals who offer care at the site of an emergency. For instance, the law grants civil immunity to a person who in good faith voluntarily gives cardiopulmonary resuscitation (CPR) to another person; a block parent volunteer who in good faith renders assistance to a minor during an emergency; and a registered member of the National Ski Patrol who in good faith and while on patrol renders emergency care at the scene of an emergency.

Opposing Argument

While naloxone has been available for many years, and some emergency responders administer it, House Bill 5404 requires medical control authorities to include protocols for each life support vehicle to be equipped with opioid antagonists and for each emergency responder to be trained in their use. Mandating those standards without providing for the cost of training responders and equipping emergency vehicles could place a burden on local units of government and may constitute an unfunded mandate, which is prohibited by the "Headlee Amendment" provisions of the State Constitution.

Response: The bill also allows medical control authorities, at their discretion, to rescind or continue the protocols after three years.

Legislative Analyst: Patrick Affholter

FISCAL IMPACT

Senate Bill 857

The bill will have no fiscal impact on State or local government.

House Bill 5404

The bill will have a minor negative fiscal impact on both State and local government. Under the requirements of the bill, the DCH must create procedures to guide the development of protocols to be implemented later by local medical control authorities. The development of these protocols will create minor administrative costs. Additionally, local governments may face an increase in costs resulting from the need to train emergency response personnel in the use of opioid antagonists as well as to equip life support vehicles with opioid antagonists.

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House Bill 5405

The bill may reduce costs to the State by reducing the number of prosecutions and convictions for prescribing or dispensing opioid antagonists as well as providing immunity to those administering an opioid antagonist in good faith. This will reduce court and corrections costs, although it is unclear how many prosecutions will be avoided. Additionally, the bill may result in savings to the State by reducing the number of investigations, hearings, and sanctions for violations of professional licensing provisions. The bill will have no fiscal impact on local government.

House Bill 5407

The bill will have a negligible negative fiscal impact on the State and no fiscal impact on local government. The annual reporting requirement contained in the bill will result in a minor increase in administrative costs for the DCH.

Fiscal Analyst: Steve Angelotti

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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.