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SFA BILL ANALYSIS

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Senate Bills 660, 661, and 662 (as enrolled) **PUBLIC ACTS 241, 242, & 235 of 2001**
Senate Bill 781 (as enrolled) **PUBLIC ACT 237 of 2001**
Senate Bills 826, 827, and 828 (as enrolled) **PUBLIC ACTS 243, 236, & 238 of 2001**
House Bill 5148 (as enrolled) **PUBLIC ACT 216 of 2001**
House Bill 5255 (as enrolled) **PUBLIC ACT 219 of 2001**
House Bills 5258 and 5259 (as enrolled) **PUBLIC ACTS 239 & 240 of 2001**
House Bills 5260 through 5263 (as enrolled) **PUBLIC ACTS 231 through 234 of 2001**

Sponsors: Senator Shirley Johnson (Senate Bill 660)
Senator Mike Goschka (Senate Bill 661)
Senator Dale L. Shugars (Senate Bills 662, 781, & 827)
Senator Bev Hammerstrom (Senate Bill 826)
Senator Alan Sanborn (Senate Bill 828)
Representative Jason Allen (House Bill 5148)
Representative Artina Hinsley Hardman (House Bill 5255)
Representative Gene DeRossett (House Bill 5258)
Representative Gary Woronchak (House Bill 5259)
Representative Thomas M. George (House Bill 5260)
Representative Paul N. DeWeese (House Bill 5261)
Representative Stephan Ehardt (House Bill 5262)
Representative Carl M. Williams (House Bill 5263)

Senate Committee: Health Policy
House Committee: Health Policy

Date Completed: 2-6-02

RATIONALE

In late 1998, Michigan voters defeated ballot Proposal B, which would have overturned State statute to allow physician-assisted suicide. Michigan was the third state in the nation to put the issue before voters. (Oregon adopted physician-assisted suicide in 1994 and again in 1997; California and Washington defeated similar proposals in the early 1990s.) The national spotlight was focused on Michigan, however, because of the actions of Dr. Jack Kevorkian. Dr. Kevorkian had invented a "suicide machine" that allowed patients to administer themselves or, in some cases, another person, with a lethal dose of drugs. Kevorkian, a Michigan physician, claimed to provide a humanitarian service to those who suffered from intractable, chronic pain. The doctor publicized his actions (including sending a videotape of an assisted suicide to the television program *60 Minutes)* and repeatedly ignored law enforcement's demands to cease attending suicides. According to *The Detroit News*, he did this to force the legal system to deal with the reality of assisted suicide.

The debate over the ending one's life in the face of pain and terminal illness had been growing for almost a century. The first euthanasia bill was drafted in Ohio in 1906, and in 1938 the Euthanasia Society of America was founded. It was not until 1969, however, when Elizabeth Kubler-Ross published *On Death and Dying,* that the larger public began to think of death as a stage of life. The book, a bestseller, examined the last days of terminally ill patients and defined the emotional stages associated with coming to terms with one's own death.

In the 1970s, the case of Karen Ann Quinlan, a young woman left in a permanent vegetative state, raised more consciousness about the right to die. Her parents fought the State of New Jersey for the right to disconnect their daughter from the machines that kept her alive. The New Jersey Supreme Court eventually concurred with the Quinlans. Their

case drew attention to living wills, which dictate a person's medical wishes should he or she become permanently unconscious or terminally ill. The wishes, however, are usually general, and tell doctors not to use "heroic measures to prolong the dying process". Because this kind of language requires interpretation, a document called an "advance directive" has become the legally preferable alternative to a living will. An advance directive names a specific person as a health care proxy or agent for another person, should that person become incapacitated and unable to communicate. The Michigan Do-Not-Resuscitate Procedure Act (Public Act 193 of 1996) affirmed in statute the right of people to refuse medical treatment at the end-of-life.

From this climate, hospice care has emerged as an increasingly popular option for care at the end of life. Hospice care offers palliative, or comfort, care for patients suffering from a terminal disease, and can be administered at home, in a hospital, or in a long-term care facility. In addition to alleviating the physical symptoms associated with a terminal disease, hospice care includes emotional and spiritual counseling for the patient, as well as household help and bereavement counseling for the patient's caregiver. Since the Federal government included hospice care in its Medicare and Medicaid coverage in 1983 and 1985, respectively, hospice care has grown at a significant rate. From 1984 to January 2001, the total number of hospices participating in Medicare rose from 31 to 2,273.

While most people presumably would agree that palliative care is a worthy cause, the primary means of pain management, controlled substances, has always generated controversy. The drugs most effective at easing pain, Schedule 2 drugs such as morphine and codeine, are considered to have the highest potential for abuse. (Please see **BACKGROUND** for more information regarding Schedule 2 drugs.) Drug addiction is not an issue for those close to death; for others suffering from long-term pain, addiction can be avoided through careful monitoring of the amount and dosage of medication, as well as through open dialogue with a consistent, careful doctor. Nevertheless, some users do become addicted and go to great lengths to obtain potent painkillers, including stealing or forging prescription pads, and "doctor shopping", in which users look for unscrupulous or unaware doctors to prescribe more drugs for them. The problem was especially heightened in the 1980s when, according to the Macomb County Department of Community Mental Health, Michigan became known as the "Miami of prescription drugs".

In response, the Michigan Legislature took measures to curtail prescription drug abuse. The State implemented the so-called "Trip-Script" program, which required doctors prescribing Schedule 2 drugs to use a special form that produced two copies of the prescription. The prescriber kept the original, and the dispensing pharmacy kept one copy and sent the other to the State. When it was revisited in the mid-'90s, the triple-copy requirement was dropped in favor of a single-copy, serially numbered form and revised reporting requirements, which allowed electronic reporting of prescription data to the State. That revised program became known as the Official Prescription Form Program (OPP), and has been considered successful at reducing diversion of Schedule 2 drugs. Some people are concerned, however, that doctors now underprescribe Schedule 2 drugs, an inadvertent consequence of the regulations. As a result, some patients reportedly do not receive the proper drug or dosage to relieve their pain.

Lack of proper of pain and symptom management was a concern for residents in the State, a finding that emerged from the work done by the Michigan Commission on Death and Dying (MCDD). The Commission, a task force formed under Public Act 270 of 1992, was charged with making legislative recommendations "concerning the voluntary self-termination of life". In addition to creating the Commission, the Act rendered assisted suicide illegal until it could be investigated further. Many of the Commission's recommendations became law under Public Act 368 of 1996, or the Michigan Dignified Death Act. (Please see **BACKGROUND** for more information on the MCDD and the Dignified Death Act.)

The 1990s, then, were a period of rapidly growing awareness about end-of-life care. One task force or commission led to another as more questions and issues were raised. The latest end-of-life task force was formed in 1999 by Governor Engler under Executive

Order (E.O.) 1999-4, which created the Michigan Commission on End of Life Care. The E.O. charged the Commission with studying State policies, and then recommending methods to remove barriers to pain management and increase public awareness of, and access to, end-of-life care.

The Commission issued its report to the Governor in August 2001. Among other findings, the report concluded that the management of patient pain and symptoms is inadequate in the State; State residents have insufficient information about, and do not exercise, available decision-making tools; and State residents lack awareness about options for treatment, especially hospice and palliative care, and thus do not fully use available services. To address these problems, the Commission recommended specific changes in policy and statute, including recommendations concerning pain and symptom management, long-term care, and patient decision-making.

CONTENT

The bills amended the Public Health Code, the Nonprofit Health Care Corporation Reform Act, the Michigan Dignified Death Act, the Insurance Code, the Michigan Vehicle Code, and Public Act 222 of 1972 (which provides for the official State personal identification card), to do the following:

-- Delete references to "intractable" pain and refer instead to "pain".
-- Refer to "reduced life expectancy due to advanced illness", instead of "terminal illness" (a six-month-or-less prognosis).
-- Require the Department of Consumer and Industry Services to establish, by rule, an electronic system for monitoring all dispensed Schedule 2-5 controlled substances.
-- Eliminate the use of the Official Prescription Program form for Schedule 2 drugs when the electronic monitoring system is operational.
-- Remove criminal penalties regarding the creation, delivery, or possession of an official prescription form.
-- Require nursing home contracts to contain information about the availability of hospice care.
-- Provide that, upon request, a hospital must provide information regarding hospice and palliative care services in the area in which the hospital is located.
-- Provide that a driver's license or a personal identification card may contain a sticker or decal that designates a patient advocate for the licensee or card holder.

Senate Bill 660

The bill amended the Public Health Code to delete references to "intractable pain" and refer instead to "pain". In addition, the bill deleted references to the Official Prescription Program.

The Code had required the Department of Consumer and Industry Services (DCIS), in consultation with the Department of Community Health (DCH), to develop, publish, and distribute an informational booklet on intractable pain. The bill, instead, requires a booklet on pain.

The bill retained a number of legislative findings on intractable pain, but deleted the term "intractable". The Code now contains legislative findings that the treatment of pain is an appropriate issue for the Legislature to consider, and that the citizens of the State would be well served by the enactment of legislation that provides more and better information to health care consumers regarding the medical treatment of pain, health care coverage and benefits for the treatment of pain, and the education of health professionals in pain and symptom management. Additional findings state that the use of controlled substances is appropriate in the medical treatment of certain forms of pain, and that some patients in this State with pain are unable to obtain from their health care providers sufficient pain relief through the prescription of controlled substances.

Further, the Code contained a statement of legislative intent to permit and facilitate adequate treatment for intractable pain by licensed health professionals. The bill deleted the word "intractable".

In addition, the bill states that it is the Legislature's intent to enable regulatory and law enforcement agencies to prevent the abuse and diversion of controlled substances by creating an electronic monitoring system.

Senate Bills 661 & 662

Senate Bills 661 and 662 amended the Nonprofit Health Care Corporation Reform Act and the Insurance Code, respectively, by deleting references to "intractable" pain in forms describing coverage.

The Nonprofit Health Care Corporation Reform Act requires Blue Cross and Blue Shield of Michigan (BCBSM) to give subscribers a form that describes the terms and conditions of the corporation's certificate. The Insurance Code also requires health insurers to give insureds a form that describes the terms and conditions of the insurers' policies and certificates. Both forms must describe, among other things, how the covered benefits apply in the evaluation and treatment of pain (previously, "intractable" pain).

The Act and the Code also require BCBSM and health insurers to provide upon request to members or insureds under prudent purchaser agreements, the professional credentials of participating health professionals, including those who are board certified in pain medicine and the evaluation and treatment of pain. Previously, these provisions had referred to the evaluation and treatment of intractable pain.

Each bill states that its changes are not to be construed as creating a new mandated benefit for any coverages issued under the statute.

Senate Bill 781

The bill amended the Michigan Dignified Death Act (Part 56a of the Public Health Code) to delete references to "terminally ill patient" and replace them with "patient with reduced life expectancy due to advanced illness" in provisions that do the following:

-- Specify that a physician is in compliance with the requirement to give certain information to a patient, patient's surrogate, or patient advocate, if the physician provides a copy of the summary of information developed by the DCH.
-- Extend civil and administrative immunity to a physician who prescribes narcotics as part of a medical treatment plan.
-- Prohibit insurers and benefits plans from taking certain actions due to a patient's decision to refuse or discontinue medical treatment.

-- Specify that Part 56a does not create a presumption about a patient's desire to receive or refuse treatment, or limit the ability of a court making a determination about a patient's decision, to consider certain State interests.

The bill also requires the DCH, by July 1, 2002, to update its written summary of information that physicians must give to such patients.

Further, the bill states that these amendments are not to be construed as creating a new mandated benefit for any coverage issued under the Insurance Code, the Nonprofit Health Care Corporation Reform Act, or any other health care payment or benefits plan.

The amendment to the section dealing with physicians' provision of information will take effect on October 1, 2002. The bill was tie-barred to House Bill 5258.

Senate Bill 826

The bill amends the Public Health Code to require nursing home contracts to contain information about the availability of hospice care. The bill takes effect on July 1, 2002.

Under the Code, a nursing home must execute a written contract with an applicant or patient, or the person's guardian or legal representative, when an individual is admitted to the nursing home, when the term of a previous contract expires, and when the source of payment for a patient's care changes. The contract must contain information specified in the Code, including the services to be provided under the contract and the charges for them. Under the bill, this information also must include the availability of hospice or other special care.

Further, the bill requires a nursing home specifically to give written notice to an applicant or patient, or that person's guardian or legal representative, of the availability or lack of availability of hospice care in the nursing home. The notice must be in a specific paragraph located in the written contract, and must require the applicant or patient, or the person's guardian or legal representative, to sign or initial the paragraph before the contract is executed. As used in these provisions, "hospice" is defined as it is in Section 20106(4) of the Code, i.e., a health care program that provides a coordinated set of services rendered at home or in outpatient or institutional settings for individuals suffering from a disease or condition with a terminal prognosis.

Senate Bill 827

The bill amends the Public Health Code by removing criminal penalties regarding the creation, delivery, or possession of an official prescription form. The bill was tie-barred to House Bills 5260, 5261, and 5262, which amended the Code to eliminate provisions that require the use of official prescription forms, and instead to require the establishment of an electronic monitoring system for dispensed controlled substances.

The Code provides that a person who manufactures, creates, delivers, or possesses with intent to manufacture, create, or deliver an official prescription form, or counterfeit official prescription form, is guilty of a felony punishable by imprisonment for up to 20 years, a fine of up to $25,000, or both. The Senate bill deletes this provision, but retains a provision that makes it a felony, punishable by up to seven years' imprisonment, up to a $5,000 fine, or both, to manufacture, create, or deliver (or possess with intent to manufacture, create, or deliver) a prescription form or counterfeit prescription form.

Further, the Code provides that a person who knowingly or intentionally possesses an official prescription form (unless obtained in a valid manner from a practitioner) is guilty of a felony punishable by imprisonment for up to one year, a fine of up to $2,000, or both. The bill deletes this provision, but retains a provision that makes it a misdemeanor, punishable by imprisonment for up to one year, a fine of up to $1,000, or both, to possess a prescription form knowingly or intentionally (unless it is validly obtained).

These amendments will take effect upon the promulgation of rules (required by House Bill 5260) and the Secretary's receipt of written notice from the DCIS Director that the electronic monitoring system is operational. The notice to the Secretary of State must state that the DCIS can receive data from at least 80% of those required to report under House Bill 5260, and can respond to requests for data from people authorized to make such requests and to review and use the data.

The Senate bill also repealed Section 17766a of the Code, which prescribed criminal penalties and licensing sanctions for the illegal use, possession, or delivery of androgenic anabolic steroids.

Senate Bill 828

The bill amended Public Act 222 of 1972 to require the Secretary of State to designate a space on the official State personal identification card where an applicant may place a sticker or decal indicating certain medical information. The bill also deleted the January 1, 2002, expiration date on a $1 service fee added to the fee for an original or renewal personal identification card.

Under the bill, a sticker or decal on a personal ID card may indicate that the cardholder carries a separate emergency medical information card. It also may be used to indicate that the cardholder has designated one or more patient advocates in accordance with the Estates and Protected Individuals Code.

The cardholder's separate emergency medical information card may contain information concerning the person's patient advocate designation, other emergency medical information, an indication as to where the cardholder has stored or registered emergency medical information, or particular medical information that must be on the personal ID card. (The Act requires a personal ID card to indicate that it contains the person's blood type, immunization data, medication data, or emergency contact information; a statement that the person is deaf; and/or a statement that the person is an organ and tissue donor.)

The sticker or decal may be provided by any person, hospital, school, medical group, or association interested in assisting in implementing the emergency medical information card, but must meet the Secretary of State's uniform size specifications.

House Bill 5148

The bill amended the Michigan Vehicle Code to provide that an operator's or chauffeur's license may contain a sticker or decal to indicate that the licensee has designated one or more patient advocates in accordance with the Estates and Protected Individuals Code, or to state that the licensee carries an emergency medical information card.

The licensee's emergency medical information card may contain information concerning the person's patient advocate designation, other emergency medical information, an indication as to where the cardholder has stored or registered emergency medical information, or the licensee's emergency contact information.

The sticker or decal may be provided by any person, hospital, school, medical group, or association interested in assisting in implementing the emergency medical information card, but must meet the Secretary of State's specifications.

House Bill 5255

The bill amended the Public Health Code to provide that, at the request of a patient, a member of the patient's family, a patient's physician, the patient's designated patient advocate, or the patient's legal guardian, a hospital must provide information orally and in writing to the requesting party regarding hospice and palliative care services, and the availability of hospice care in the area in which the hospital is located. The hospital must provide the information whether or not the hospital provides hospice care.

House Bill 5258

The bill amended the Michigan Dignified Death Act to do the following:

-- Remove the Act's definition of "terminal illness" and replace certain references to terminal illness with the phrase "reduced life expectancy due to advanced illness".
-- Require physicians to inform patients with reduced life expectancy due to advanced illness that they may choose pain and symptom management.
-- Declare a legislative finding that health care providers should be encouraged to initiate discussions of medical directives with their patients during initial consultations, annual examinations, hospitalizations, at diagnosis of a chronic illness, and upon transfer from one health care setting to another.

The Act previously defined "terminal illness" as "a disease or condition due to which, in the opinion of a physician, a patient's death is anticipated within 6 months after the date of the physician's opinion". The bill removed the definition, and in general replaced references to the phrase with "reduced life expectancy due to advanced illness". The bill states the following: "'Advanced illness', except as otherwise provided in this subdivision, means a medical or surgical condition with significant functional impairment that is not reversible by curative therapies and that is anticipated to progress toward death despite attempts at curative therapies or modulation, the time course of which may or may not be determinable through reasonable medical prognostication." (The exception to this definition applies to subdivision 5655(b), which confers rights on the patient, the patient's surrogate or the patient advocate to make an informed decision regarding receiving, continuing, discontinuing, and refusing medical treatment for the patient's reduced life expectancy due to advanced illness. Under the bill, in this subdivision only, "advanced illness" has the same general meaning as "terminal illness" has in the medical community.)

Under the Act, a physician recommending medical treatment for terminal illness must inform the patient, the patient advocate, or the patient surrogate about the patient's rights and options during the course of treatments. In addition to this information, the bill requires a physician who has diagnosed a patient as having a reduced life expectancy due to an advanced illness to inform the patient, the patient advocate, or the patient surrogate that he or she may choose adequate and appropriate pain and symptom management as a basic and essential element of medical treatment. These amendments will take effect October 1, 2001.

The bill provides that it may not be construed as creating a new mandated health care benefit for any coverages issued under the Insurance Code, the Nonprofit Health Care Corporation Reform Act, or any other health care payment or benefits plan. The bill was tie-barred to Senate Bill 781.

House Bill 5259

The bill amended Part 201 of Article 17 of the Public Health Code, which prescribes general regulations for health care facilities and agencies, to require the rights and responsibilities policy adopted by a facility or agency to include the following: "A patient or resident is entitled to adequate and

appropriate pain and symptom management as a basic and essential element of his or her medical treatment."

Part 201 requires a licensed health facility or agency that provides services directly to patients or residents to adopt a policy describing the rights and responsibilities of patients or residents. The policy must be posted in a public place and must include provisions regarding the right to appropriate care, regardless of race, religion, disability, etc.; the right to information about their medical condition and treatment; confidential treatment of personal and medical records; freedom from mental or physical abuse; and the right to refuse treatment, among others. In the case of a nursing home patient, these rights can be exercised by the patient's representative.

House Bill 5260

Controlled Substances Monitoring

Article 7 of the Public Health Code governs controlled substances. The bill amended Article 7, Part 73, which deals with the manufacture, dispensing, and distribution of controlled substances. The bill requires the DCIS to establish, by rule, an electronic system for monitoring Schedule 2, 3, 4, and 5 controlled substances dispensed in Michigan by veterinarians, and by licensed pharmacists and dispensing prescribers (doctors and dentists who dispense prescription drugs to their own patients); or dispensed to a Michigan address by a pharmacy licensed in the State. The rules must provide an appropriate electronic format for the reporting of data, including patient identifiers, the name of the controlled substance dispensed, date of dispensing, quantity dispensed, prescriber, and dispenser. The DCIS must require a veterinarian, pharmacist, or dispensing prescriber to use the electronic data transmittal process developed by the Department or its contractor.

A veterinarian, pharmacist, or dispensing prescriber may not be required to pay a new fee dedicated to the operation of the electronic monitoring system, or incur any additional costs for the transmission of data to the Department. The rules promulgated under the bill must exempt from the reporting requirements the administration of a controlled substance directly to a patient; and the dispensing from a licensed health facility or agency of a controlled substance by a dispensing prescriber, in a quantity adequate to treat a patient for not more than 48 hours.

Not withstanding any practitioner-patient privilege, the DCIS Director may provide data obtained under these provisions to all of the following:

-- A designated representative of a board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances.
-- An employee or agent of the Department.
-- A State, Federal, or municipal employee or agent whose duty is to enforce the laws of the State or the United States relating to drugs.
-- A State-operated Medicaid program.
-- A State, Federal, or municipal employee who holds a search warrant or subpoena properly issued for the records.
-- A practitioner or pharmacist who requests information and certifies that it is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient.
-- An individual with whom the DCIS has contracted to administer the system.

A person who receives data or any report containing any patient identifiers of the system from the DCIS may not provide it to any other person or entity, except by court order. Except as otherwise provided in Part 73, information submitted under these provisions may be used only for bona fide drug-related criminal investigatory or evidentiary purposes or for investigatory or evidentiary purposes in connection with a disciplinary subcommittee or one or more of the licensing or registration boards created in Article 15 of the Code.

The DCIS, all law enforcement officers, all officers of the court, and all regulatory agencies and officers, in using the data for investigative or prosecution purposes, must consider the nature of the prescriber's and dispenser's practice and the condition for which the patient is being treated. The data and any report containing any patient identifiers obtained from them are not public records or subject to the Freedom of Information Act.

The DCIS may issue a written waiver of the electronic reporting requirement to a veterinarian, pharmacist, or dispensing prescriber who establishes grounds that he or she is unable to use the electronic monitoring system. The DCIS must require the applicant for the waiver to report the required information in a manner approved by the Department.

Under the Code, the Controlled Substances Advisory Commission is required to monitor consumption of controlled substances in Michigan, and issue an annual report to the Governor, Legislature, and Michigan Board of Pharmacy on the status of the abuse and diversion of controlled substances. The bill requires the Commission to include in its annual report information on the implementation and effectiveness of the electronic monitoring system.

In consultation with the Commission, the Michigan Board of Pharmacy, the Michigan Board of Medicine, the Michigan Board of Osteopathic Medicine and Surgery, the Michigan State Police, and appropriate medical professional associations, the DCIS must examine the need for the production of a prescription form on paper that minimizes the potential for forgery. The DCIS may promulgate rules for the production of the form, but the rules may not include any requirement that sequential numbers, bar codes, or symbols be affixed, printed, or written on a prescription form, or that the form be produced by the State. In examining the need for rules for the production of a form, the DCIS must consider and identify the cost, benefits, and barriers; the overall cost-benefit analysis; and compatibility with the electronic monitoring system.

The DCIS must report its findings on the need for a prescription form to the members of the House and Senate standing committees having jurisdiction over health policy issues, by October 1, 2002, and before the electronic monitoring system becomes operational.

Official Prescription Form/Prescription Form

The amendments and repeals described below take effect upon the promulgation of the rules required under the bill for an electronic monitoring system, and receipt by the Secretary of State of written notice from the DCIS Director that the system is operational. The notice must state that the Department can receive data from at least 80% of those required to report under the bill, and can respond to requests for data from people authorized to make such requests and to review and use the data.

Section 7334 of the Code requires official prescription forms to be used for prescriptions for Schedule 2 controlled substances; requires the DCIS to issue the forms to practitioners; prescribes certain requirements for the content of the forms; and requires prescribers to follow specified procedures when using the forms. The bill repeals Section 7334.

The bill also repeals Section 17766b, which requires a prescription for an androgenic anabolic steroid to be recorded on an official prescription form in the manner that is required for Schedule 2 prescriptions.

The bill retains provisions that prohibit a practitioner from issuing more than one prescription for a Schedule 2 controlled substance on a single form, and prohibit a prescribing practitioner from postdating a prescription form that contains a prescription for a controlled substance.

Currently, except for a terminally ill patient, a prescription for a Schedule 2 controlled substance may not be filled more than five days after the prescription was issued. The bill allows up to 60 days. In addition, the Code allows a practitioner to prescribe orally a Schedule 2 drug in an emergency situation if the practitioner promptly fills out an official prescription form and forwards it to the dispensing pharmacy within 72 hours. The bill allows up to seven days, and deletes reference to an "official" prescription form. (Article 7 defines "practitioner" as "a prescriber or pharmacist, a scientific investigator as defined by rule of the administrator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state...", or a pharmacy, hospital, or other institution or place of professional practice licensed, registered, or otherwise permitted to do so.)

The bill allows a prescriber to transmit a prescription by facsimile of a printed prescription form, and by electronic transmission of a printed prescription form, if

not prohibited by Federal law. If, with the patient's consent, a prescription is electronically transmitted, it must be transmitted directly to a pharmacy of the patient's choice, and the data may not be altered, modified, or extracted in the transmission process.

The bill establishes a "good faith" standard for the dispensing of controlled substances, by providing that a practitioner "in good faith" may dispense a Schedule 2, 3, 4, or 5 controlled substance upon receiving a prescription. The bill defines "good faith" as the prescribing or dispensing of a controlled substance by a licensed practitioner in the regular course of professional treatment to or for an individual who is under treatment by the practitioner for a pathology or condition other than that individual's physical or psychological dependence upon or addiction to a controlled substance, except as provided in Article 7. Application of good faith to a pharmacist means the dispensing of a controlled substance pursuant to a prescriber's order that, in the pharmacist's professional judgment, is lawful. In making the judgment, the pharmacist must be guided by nationally accepted professional standards, including all of the following:

-- Lack of consistency in the doctor-patient relationship.
-- Frequency of prescriptions for the same drug by one prescriber for large numbers of patients.
-- Quantities beyond those normally prescribed for the same drug.
-- Unusual dosages.
-- Unusual geographic distances between patient, pharmacist, and prescriber.

In addition, the bill deletes provisions for the prescription and dispensing of androgenic anabolic steroids.

Tie-Bar

The bill was tie-barred to Senate Bill 827 and House Bills 5261 and 5262.

House Bill 5261

The bill amended the Public Health Code to abolish the Official Prescription Form Program Fund and create a "Pain Management Education and Controlled Substances Electronic Monitoring and Antidiversion Fund". Previously, the Program Fund received $20 from each $75 annual licensing fee paid to the DCIS for persons licensed to manufacture, distribute, prescribe, dispense, or conduct research with controlled substances. Money in the Fund could be used only for programs relating to official prescription forms. The bill required that money in the Program Fund on the bill's effective date be transferred to the Monitoring and Antidiversion Fund. The $20 from the annual licensing fees must be deposited in the new Fund. The DCIS may use the Fund only in connection with programs relating to pain management education for health professionals, preventing the diversion of controlled substances, and maintenance of the electronic monitoring system for controlled substances data required under House Bill 5260.

House Bill 5261 requires the State Treasurer to direct the investment of the Fund. Interest and earnings from the investments must be credited to the Fund. The unencumbered balance in the Fund at the close of the fiscal year must remain in the Fund and not revert to the General Fund. The Fund may receive gifts and devises and any other money as provided by law.

The bill was tie-barred to Senate Bill 827 and House Bills 5260 and 5262.

House Bill 5262

The bill amends Part 71 of the Public Health Code, which defines terms used in Article 7. The bill deletes the definition of "official prescription form", and revises the definition of "prescription form".

Currently, "official prescription form" means a prescription form for a Schedule 2 controlled substance that meets the requirements of Section 7334 and is issued to practitioners by the DCIS. (Section 7334 is repealed by House Bill 5260.)

"Prescription form" currently means a printed form that is authorized and intended for use by a prescribing practitioner to prescribe controlled substances or other prescription drugs and that meets the requirements of rules promulgated by the administrator (the Board of Pharmacy). The bill also requires a prescription form to include the following:

-- The preprinted, stamped, typed, or

manually printed name, address, and telephone number or pager number of the prescribing practitioner.
-- The manually printed name of the patient, the address of the patient, the prescribing practitioner's signature, and the prescribing practitioner's Drug Enforcement Administration (DEA) registration number.
-- The quantity of the prescription drug prescribed, in both written and numerical terms.
-- The date the prescription drug was prescribed.

In addition, a prescription form must meet the requirements of any rules promulgated by the Department (pursuant to House Bill 5260).

The bill defines "electronic signature" as an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record. Further, "sign" means to affix one's signature manually to a document or to use an electronic signature.

The bill takes effect upon the promulgation of the rules by the DCIS under House Bill 5260, and the Secretary of State's receipt of written notice from the DCIS Director that the required electronic monitoring system is operational. The notice to the Secretary of State must state that the DCIS can receive data from at least 80% of those persons required to report under House Bill 5260, and can respond to requests for data from persons authorized to make such requests and to review and use the data.

The bill was tie-barred to Senate Bill 827 and House Bills 5260 and 5261.

House Bill 5263

The bill amended Section 16204a of the Public Health Code to delete references to "intractable" pain and refer instead to pain and symptom management.

Section 16204a provides for an Advisory Committee on Pain and Symptom Management within the Department of Community Health, and prescribes the membership of the committee. Previously, several members, including a registered professional nurse, a dentist, a pharmacist, and a physician's assistant, had to have training in the treatment of intractable pain. Under the bill, these individuals must have training in pain and symptom management.

Under Section 16204a, "intractable pain" meant "a pain state in which the cause of the pain cannot be removed or otherwise treated and which, in the generally accepted practice of allopathic or osteopathic medicine, no relief of the cause of the pain or cure of the cause of the pain is possible or none has been found after reasonable efforts, including...evaluation by the attending physician and by 1 or more other physicians specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain". The bill deleted this definition.

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550.1402a (S.B. 661)
500.2212a (S.B. 662)
333.5656-333.5660 (S.B. 781)
333.21766 (S.B. 826)
333.7401 et al. (S.B. 827)
28.292 (S.B. 828)
257.310 (H.B. 5148)
333.21534 (H.B. 5255)
333.5652-333.5655 (H.B. 5258)
333.20201 (H.B. 5259)
333.7333 et al. (H.B. 5260)
333.16315 (H.B. 5261)
333.7104 et al. (H.B. 5262)
333.16204a (H.B. 5263)

BACKGROUND

Controlled Substance Schedules

The Public Health Code classifies controlled substances under five schedules. By definition, all scheduled drugs have the potential for abuse and are either illegal and without any medically accepted use in the United States (all Schedule 1 drugs) or prescription drugs with medically accepted uses in the U.S. but a potential for psychological or physical dependence (Schedules 2, 3, 4, and 5). Schedule 1 and 2 drugs are defined as having a "high risk" of abuse, and drugs on Schedule 2-5 have successively reduced potential for leading to dependence.

Schedule 2 prescription drugs include opium and its derivatives (e.g., codeine, morphine, and oxycodone), opium poppy and straw, other opiates, methadone, and pethidine, coca leaves and derivatives, such as cocaine, and methylphenidate. Schedule 2 also includes

substances containing any quantity of such drugs as amphetamine and methamphetamine, methaqualone, and barbiturates.

Schedule 3 includes, among other things, substances with any quantity of a derivative of barbituric acid and drugs containing limited quantities of opium, codeine, or morphine. Schedule 4 includes drugs such as diazepam, barbital, chloral hydrate, lorazepam, meprobamate, and phenobarbital.

Official Prescription Program

Under Public Act 60 of 1988, the Michigan triplicate prescription program (TPP) and the Michigan Controlled Substances Advisory Commission were established. Previously, the law required only that controlled substances not be dispensed without the written prescription of a licensed practitioner, with some exceptions for emergency situations. The TPP required that prescriptions for Schedule 2 drugs be written on an official prescription form, and that no more than one prescription be written on a single form. An "official prescription form" was defined as a serially numbered, triplicate form containing spaces for the following information: the date the prescription was written and the date it was filled; the controlled substance prescribed, the dosage, and instructions; the name, address, and DEA number of the dispensing pharmacy and the initials of the pharmacist who filled the prescription; the name, address, and age of the person for whom the substance was prescribed; and the name, address, and age of the patient or, in the case of an animal, its owner, for whom the controlled substance was prescribed.

The prescriber was required to fill in all three copies of the form, keep the bottom copy in his or her records for five years, and give the patient the first two copies. The patient took the copies to the pharmacist, who was required to keep one copy on record for at least five years and send the other to the State by the 15th of the month.

In April 1993, the Commission issued a report evaluating the TPP. It found the TPP very successful at reducing diversion of controlled substances, but recommenced a number of changes to the program, several of which were incorporated in Public Act 138 of 1993. Specifically, the Act retained the Official Prescription Form Program, but replaced the triplicate form with a single-copy prescription form, effective January 1, 1995. The form contains the same information as the TPP. When the pharmacist receives the official prescription form, he or she must forward the form to the State or transmit the information electronically or on storage media. The Department of Commerce (subsequently replaced by the DCIS) was required to develop a standardized database format for transmitting information electronically or on storage media by the end of 1993. The Act also dropped methylphenidate (Ritalin) from the OPP.

The 1993 Act that extended the OPP mandated that by September 30,1997, the Department of Commerce submit a report to the Governor, Legislature, and certain other parties on request. The report was required to evaluate the following: the effectiveness of the OPP in reducing the diversion of Schedule 2 drugs; any related increase in the use of Schedule 3, 4, and 5 drugs; the program's cost-effectiveness; the use of electronic or storage media to transfer data; the use of the single copy official prescription form; and any changes the Department recommended be made in the program. In 1997, the Department of Consumer and Industry Services submitted its report, which was prepared by the Office of Health Services in conjunction with the Commission. (A full copy of the 1997 report, including appendices, is available on the DCIS website.)

Assisted Suicide and the Michigan Commission on Death and Dying

In 1992, the Michigan Legislature made "assistance to suicide" a crime under Public Act 270. As part of the Act, the Michigan Commission on Death and Dying (MCDD) was established, and charged with developing recommendations on legislation regarding "voluntary self-termination of life". The Commission was made up of 22 members representing a range of organizations, including the American Civil Liberties Union, the American Association of Retired Persons, the Hemlock Society of Michigan, the Michigan Association for Retarded Citizens, the Michigan Hospice Organization, the Michigan State Medical Society, Right to Life of Michigan, and the State Bar of Michigan, among others. Fifteen months after the enactment of the law, the Commission was to publish a report of its

findings, which was to include, in part, the role age, disease, disability, and pain played in the decision to terminate one's life; the laws of other states regarding assisted suicide; and a societal consensus, if it existed, on the issue. The Act provided for its own repeal six months after both houses of the Legislature received the report.

The Commission on Death and Dying held meetings, heard testimony, and collected information. It became clear that no consensus on the question of whether assisted suicide should be decriminalized would be reached. The Commission did, however, arrive at some points of agreement about the Legislature's role in end-of-life care. In its final report, the MCDD wrote that the Legislature should educate the public about advance health care directives, patient control over medical treatment, and the right to treatment for pain and other distressing symptoms. In addition, the MCDD recommended that the Legislature take action to augment suicide prevention initiatives, ensure the referral of those who inquired about suicide to experts who could assist the them in acquiring services to alleviate their suffering, improve access to palliative care and hospice services, and modify the use of the Trip-Scrip program for those with severe pain.

The Michigan Dignified Death Act

The Michigan Commission on Death and Dying found that a competent adult has the right to self-determination with regard to choosing or refusing medical treatment and has the right to treatment for pain and other distressing symptoms. The MCDD also found that a competent patient has the right to refuse medical treatment and the right to the treatment of pain and other symptoms of a disease, even if the refusal or treatment unintentionally hastens or increases the risk of the patient's death. These findings provided the background for Public Act 368 of 1996, or the Michigan Dignified Death Act.

The Act required that physicians inform "terminally ill" patients about alternative medical treatments, their right to designate a patient advocate, and their right make an informed decision concerning medical treatment. Further, the Act provided that a physician who prescribed a Schedule 2-5 narcotic drug in good faith and with the intent of treating a patient with a terminal illness or alleviating a patient's pain, or both, was immune from civil, criminal, and administrative liability for the prescription. "Terminal illness" was defined as a "disease or condition due to which, in the opinion of a physician, a patient's death is anticipated within six months after the date of the physician's opinion".

Michigan Commission on End of Life Care

Executive Order 1999-4, issued on June 11, 1999, created the 17-member Michigan Commission on End of Life Care in the Department of Community Health. Charges to the Commission included identifying, compiling, and considering recommendations for improving end of life care from public and private organizations throughout Michigan; recommending model state and institutional policies with respect to end of life care; identifying and evaluating existing barriers that result in inadequate end of life care, and making recommendations for the elimination or mitigation of those barriers; evaluating the adequacy of end of life care education for health professionals; surveying the availability and cost of public and private insurance coverage for hospice, pain management, and palliative care; and inventorying existing resources available to citizens for end of life planning. The E.O. required the Commission to issue a final report to the Governor and the Legislature within 15 months.

On January 24, 2000, the Governor issued Executive Order 2000-2, which reduced the size of the Commission to 12, and delayed the deadline for its final report to February 1, 2001. A copy of the Commission's report is available on the DCH website.

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

This package of legislation implements in statute a number of recommendations made by the Commission on End of Life Care. As the Commission recognized, people facing the end of their lives should have optimal comfort and support, but many barriers deny appropriate end of life care to those who need

it. This legislation will help to overcome some of those barriers, particularly in regard to adequate pain and symptom management. The bills also will enhance the ability of individuals and their families to decide what is best for patients approaching death. Over the past decade, Michigan has taken many steps to explore and address end of life issues. The enactment of these bills represents significant progress toward the humane treatment of a very vulnerable population: individuals who are living and dying with advanced illness and severe pain.

Supporting Argument

Senate Bills 660-662 and House Bill 5263 are correct to delete the word "intractable" from current statutes. The word, as defined by the third edition of the American College Dictionary, means "difficult to alleviate, remedy, or cure". To many people, the word connotes a notion of agony, of a pain that will not yield, even to opiates. Studies show that patients are reluctant to catagorize their pain as intractable. As a result, medical professionals have developed other methods to gauge pain. Asking a patient to rate his or her discomfort on a scale of 1-10, for example, provides a clearer indication of that patient's pain at that moment. Merely asking the patient if his or her pain is intractable implies that there is an objective standard for pain and that the pain must be unbearable.

Use of the term "intractable pain" can result in patients' underreporting their pain, which in turn can result in physicians' and nurses' undertreating it. With proper treatment, no pain should be intractable. Changing Michigan statutes and the patient bill of rights to reflect this should help bring about better pain and symptom management.

Supporting Argument

Senate Bill 781 and House Bill 5258, which amend the Dignified Death Act by replacing the definition of terminal illness, will improve patients' access to hospice care. Terminal illness bound by a six-month-or-less prognosis is an American invention based on a financial rationale. The definition exists to limit the Medicare or Medicaid hospice benefit to those very close to death, as opposed to those who are chronically ill. It has no basis in clinically validated, scientific studies. There are several reasons to eliminate this definition of terminal illness in Michigan statutes.

First, physicians resist the six-month prognosis determination. Because prognostication is not an exact science and cannot be precisely determined for an individual patient, physicians are reluctant to "guestimate" about such a significant matter. Doctors report that they are uncomfortable communicating an indeterminate, unscientific prognosis to patients and families who turn to them for treatment. In addition, many physicians are well aware that a patient's condition can dramatically decline following a declaration that he or she has less than six months to live, perhaps because the physician's judgment is heard as a truth not to be disputed.

Next, the six-month prognosis impedes legitimate access to the Medicare/Medicaid hospice benefit. Reportedly, hospice providers fear that they will be scrutinized or sanctioned if they have a Medicare or Medicaid patient who lives longer than six months. In response, many patients may be discouraged from signing onto hospice until late in their illness, or they may be discharged from hospice if they live longer than six months. These realities are reflected in the decrease in average lengths-of-stay in hospice. While the number of hospice patients has increased, the number of days the average patient is under hospice care has decreased on the State and national levels.

Last, the six-month prognosis excludes terminally ill patients who are best cared for under a hospice approach, but are deemed ineligible. According to Hospice of Michigan, the State's experience with Dr. Jack Kevorkian and the ensuing physician-assisted suicide ballot proposal demonstrated that approximately 75% of patients seeking such assistance were not terminally ill by current definition. Chronically ill people and their families are in serious need of comfort and support, but most are ineligible for the Medicare/Medicaid hospice benefit because of this definition. Services provided by hospice and paid for under this benefit include home visits by a spiritual advisor, a social worker, and a doctor and nurse trained in palliative care; yet these valuable resources must go unused by people suffering from Lou Gehrig's Disease, Multiple Sclerosis, Alzheimer's Disease, and many other painful diseases because of an arbitrary definition.

Supporting Argument

Senate Bill 828 and House Bill 5148 authorize the application of stickers or decals to a State identification card or a driver's license to indicate that the cardholder has designated a patient advocate or that he or she carries a separate emergency medical card. It is important to carry such information on one's person because an advance directive, advocate designation, do-not-resuscitate order, or emergency medical information (such as whether a person has diabetes or epilepsy) is effective only if readily accessible. A driver's license or State personal identification card is a logical place to hold such information. Medical personnel will know to look for the decals, thus making a profound, important decision (whether to sustain life support, for example) more tenable. In addition, the decals might resolve a question of legal competence or authority. If a patient's family member or friend claims to know the medical wishes of the patient, but has no verifiable proof, then complications can result. A decal informing medical personnel that a patient holds an emergency card or has a patient advocate can help ensure that a patient's wishes are followed.

Response: The new decal might present an additional liability for medical personnel who do not or cannot locate the sticker. Emergency medical technicians and emergency room nurses and doctors are under a great deal of pressure to make rapid decisions, and it will not benefit anyone to contribute to this pressure.

Supporting Argument

Senate Bill 826 requires nursing home contracts to provide information about the availability of hospice care, and House Bill 5255 requires health care facilities, such as hospitals, to provide the information to patients upon request of a patient, family member, or patient advocate. Both bills increase the decision-making power of the patient and family. According to the Commission on End of Life Care, the biggest single barrier to consumers' ability to make decisions about the care at the end of their lives is "lack of education in...patient rights, advance directives, designation of surrogates for end-of-life decision-making, and the options for treatment, including hospice and palliative care". The report also recognizes that too often patients "do not understand the relationship between curative and palliate care or know that pain and symptoms can be managed without forgoing all options for curative care". These bills, along with House Bill 5258,
help to removing the barrier to patient empowerment identified by the Commission.

Supporting Argument

House Bill 5260, which replaces the Official Prescription Form Program with an electronic monitoring system, will benefit patients and doctors. The Michigan Commission on End of Life Care found that the OPP was one of the most significant impediments to proper pain management. In a Commission survey of doctors, 39% of the practitioners said they feared regulatory scrutiny when prescribing Schedule 2 drugs. According to the survey, some physicians prescribed a Schedule 3 or Schedule 4 drug to avoid scrutiny, in spite of the fact that these drugs are less effective on pain and can have serious side effects on the gastric system or kidneys. In fact, some Schedule 4 drugs, such as Valium, Ativan, and Xanax, are more widely abused than Schedule 2 drugs, perhaps because doctors and patients view them as safe. Indeed, the 1997 Evaluation Report released by the Controlled Substances Advisory Commission revealed both a dramatic decrease in prescriptions for Schedule 2 drugs and a dramatic increase in the forgeries of scripts for Schedule 3 and 4 drugs. (For example, the number of oxycodone scripts cashed was down 41% from 1990 to 1995, while the forgeries for Schedule 3 and 4 drugs were up 43% in the same period.)

The abuse of opiod analgesics, which include Percodan, OxyCotin, and Dilaudid, has been exaggerated, and so has the effectiveness of the OPP. In fact, neither Federal nor State agencies have kept records of arrests or convictions of drug abuse, before or during the OPP. All stories of the OPP's success are purely anecdotal. Some hard data on emergency room visits conducted by DAWN, the Drug Abuse Warning Network sponsored by the Federal government, suggest an almost insignificant drop in opiod overdoses from 1988 to 1999. According to the analysis, opiod analgesic overdoses dropped from 4% to 2% during that time period; these numbers are identical to those reflecting overdoses due to nonopiod analgesics, such as aspirin and acetaminophen. Illicit drugs–
cocaine, heroin, LSD, etc.–represented the greatest percentage of overdoses, at 40% in 1988 and 48% in 1999.

The electronic monitoring system has the potential to correct the problems at the heart of the OPP. First, because all prescriptions, regardless of schedule, will be submitted to the State electronically, the stigma of Schedule 2 drugs will be eliminated. Next, the system will allow for efficient analysis of prescription data. The copies of scripts kept under the Trip-Script program and the OPP are so voluminous that they are almost worthless. Currently, the copies are examined only when a specific practitioner or patient is under investigation; the data are not used to measure the quality of pain management in the State. Under an electronic system, data analysis will be easy. In Illinois, for example, doctors can use the system to view their own prescribing behavior. On a larger scale, the DCIS could analyze prescribing trends for the whole State to help medical associations target educational efforts for improved pain management. Further, the electronic system will be more useful for law enforcement agencies. According to an article in *The New York Times* (December 21, 2001), Kentucky drug enforcement authorities used that state's electronic system to find and arrest 252 people for abuse of OxyContin.

Even if the anecdotal evidence about the OPP's success is accurate, another fact looms larger: Michigan's residents are not receiving the pain care they need. For example, a study for the Robert Wood Johnson Foundation found that Michigan nursing home patients suffer from pain: During one visit, 45.3% of the patients reported pain; of them, 9.2% had excruciating pain. Sixty days later, a follow-up study found that 39.2% of the patients had worsening pain. It is no better in hospitals; a 1996 Detroit Medical Center study found that, in a 24-hour period, the patients' pain averaged 7.2 on a scale of 10, as reported by the patients. It is only on hospice that many sufferers find relief. A Michigan Hospice and Palliative Care survey found that over 30% of patients admitted to hospice are in severe pain, but many are surprised when their pain is relieved through hospice drug protocols. With appropriate drug management, no pain should be intractable. Implementing the electronic system will reduce the stigma, confusion, and fear of Schedule 2 opiod analgesics so that they may be properly prescribed to those in pain.

Opposing Argument

Removing the definition of "terminal illness" from State statute will not change Americans' cultural attitudes about death and dying. Many people are reluctant to sign onto hospice care because they fear giving up curative treatments. This reluctance is reflected in increasingly shorter lengths-of-stay in hospice. It seems illogical and counterproductive to extend a benefit that is not used to its fullest extent. Furthermore, changing State statute will not alter Federal statute and the Medicare/Medicaid benefit limit of six months. While deleting the terminal illness definition might result in patients' staying in hospice longer, they could do so without insurance or Medicaid coverage.

Response: The definition of "terminal illness" does not meet the needs of patients, their families, or their physicians. Referring instead to "patient with reduced life expectancy due to advanced terminal illness" more adequately describes chronically ill patients. Amending State statute might encourage Federal agencies to do the same, thus allowing more eligible patients to receive the end-of-life care they deserve, as well as the insurance or Medicare/Medicaid benefit to cover it.

Opposing Argument

The Official Prescription Form Program has virtually eliminated forged prescriptions of Schedule 2 drugs. According to the Controlled Substances Advisory Commission, there has not been a single documented case in which a fraudulent official prescription form has been produced and cashed at a pharmacy. Official prescription forms reported stolen by the prescriber and then cashed were fewer than five. Completely eliminating such a successful program might regress Michigan to the 1980s, when the State was the first in the nation in the consumption of several Schedule 2 and 3 drugs. A 1989 Controlled Substances Advisory Commission survey reflected pharmacists' estimates that approximately 104,000 pills per year reached the illegal market annually, before the adoption of the Triplicate Prescription Program. In addition, State and Federal law enforcement agencies have indicated that there has been a dramatic decrease in the availability of prescription Schedule 2 drugs in the illicit market since 1989. The agencies have argued that the official prescription form has a psychological deterrent value.

Eliminating special forms or paper for Schedule 2 drugs will result in increased drug

diversion to addicted users or drug dealers, because a computer database will be slow to flag illicit activity. (Presumably, there will be a lag time between the writing of the prescription and its entry in a computer, and another delay before the data are analyzed.) A dealer might visit a dozen drugstores in a day with forged prescriptions before the State or pharmacies know what is happening. Creating false prescriptions is relatively easy if special paper is not required; individuals can go to a local printer or copy center to make their own prescription pads. There is even a site on the Internet titled, "How to Write Your Own Prescriptions". The author of the site assures readers that prescriptions are remarkably easy to fake because most scripts do not contain special ink, watermarks, bar codes, or serial numbers. The DEA affirms that states that rely solely on electronic systems lose some measure of protection against forged and altered prescriptions.

Claims that Michigan's electronic monitoring system is modeled after a successful program in Kentucky are misleading. Kentucky's system still requires special paper prescription forms for certain drugs, and it does not allow for electronic prescribing *by the doctor to the pharmacy*; rather, it only permits electronic transfer of information *from pharmacies to the state*, according to the Macomb County Prosecuting Attorney. Under House Bill 5260 and 5261, all prescription transactions can take place electronically (if allowed by Federal law), thus increasing the chance for tampering.

If the purpose of the system is to monitor physician prescribing patterns and patient drug consumption while avoiding a stigma for Schedule 2 drugs, then special, forgery-proof paper should be used in tandem with the electronic system and required for *all* prescriptions. The paper could be modeled after Idaho's requirements, believed to be the gold standard for preventing forgery. There, the paper contains a copy ban capture and a chemical capture (i.e., the word "void" will appear if the paper is copied or if chemicals are used to alter the paper); an artificial watermark; and thermocromatic ink used for the "Rx", which disappears when rubbed with the fingers. While this paper is expensive, it should be considered part of the cost of doing business, no different than the added cost of using child-proof medicine containers.

Lastly, the goal of using special paper or State-issued forms is to reduce illegitimate use of prescription drugs; it is not to keep doctors from prescribing pain medication to patients who need it. Doctors who are not overprescribing will not be sanctioned; in fact, no disciplinary action has ever been taken when the prescriptions were within the scope of practice and medically justified. If prescribers feel a chilling effect from the OPP, then that is a result of a misunderstanding of the program's goals. Efforts should be focused on educating physicians, not on eliminating a very effective system.

Response: House Bill 5260 does not preclude the use of special, forgery-proof paper; instead, the bill requires the DCIS to "examine the need for...the production of a prescription form on paper that minimizes the potential for forgery". It is possible that the DCIS will decide that tamper-proof paper is worth the expense and trouble if its use would cut down on forgery.

That said, the electronic system might make paper obsolete. Under this system, it is permissible for a doctor to transmit a prescription electronically or by facsimile directly to a pharmacy, if not prohibited by Federal law. The head administrator of the electronic reporting system in Kentucky reported that physicians liked the electronic system but found the mandatory special paper form cumbersome and unnecessary. In the foreseeable future, perhaps all prescriptions will be transmitted to a pharmacy via a secure electronic system, thus eliminating the concern about forged paper prescriptions.

Opposing Argument

If doctors fear scrutiny under the Official Prescription Form Program, that fear could increase under the electronic system, which will track *all* prescriptions of controlled substances. This dread of "Big Brother" might result in the underprescription of all scheduled pain medication. Since the system also will monitor the activities of patients, people might drive to neighboring states to have their prescriptions filled. A *The New York Times* article (December 21, 2001) reported this very behavior following the implementation of Kentucky's electronic monitoring system; that is, patients were taking their prescriptions for opiods to neighboring states to have them filled because of fear *they* would be scrutinized.

Opposing Argument

House Bill 5259 amended the Patient Bill of Rights, found in the Public Health Code, to include "basic pain and symptom management" as an essential element of medical treatment. While this addition will be beneficial, pain and symptom management is only half of the End of Life Commission's recommendation regarding the Patient Bill of Rights. The right to hospice and palliative care is the other half. Omitting reference to these essential components of end-of-life care may perpetuate societal prejudices against them, thus failing to extend adequate care to patients.

"Palliative care" means comfort care and uses treatments that reduce physical suffering. Hospice care encompasses palliative care and includes spiritual, social, and emotional support. Placing both terms in the Patient Bill of Rights could change the belief that hospice care is for those who have "given up". It seems that this belief is in part responsible for the underuse of hospice, according to the American Cancer Society. Death is a part of life, yet Americans tend to deny the reality of death and attempt to fight it until the end. All people with terminal illness should have, as a basic right, access to reduced physical and emotional suffering.

Significantly, hospice care has been an entitlement for any Medicare and Medicaid patient since 1983 and 1985, respectively. This underscores the Federal government's commitment to providing adequate end-of-life care to the nation's citizens; it is time the State did the same.

Response: Including palliative and hospice care in the Patient Bill of Rights would create a broad requirement and could pose liability problems for insurance providers and/or hospitals. If for some reason a patient were not eligible for hospice care, for example, an insurance company could be sued. Further, broad language entitling patients to hospice care could be interpreted as mandating all hospitals to provide it, which is not economically feasible for many small or rural hospitals.

Opposing Argument

The bills do not address some key points of the Commission on End of Life Care's report. Foremost, the bills ignore the issue of hospice reimbursement. According to the Commission's report, approximately 70% of those who die in any given year are covered by Medicare, and about 13% are covered by Medicaid. Despite the wide range of hospice services covered by these programs, Medicare and Medicaid do not reimburse fully for certain hospice costs. For example, Medicare does not pay room and board costs for patients receiving hospice care services; this affects nursing home residents who want hospice care to be administered in the facility. Furthermore, the Commission found that the Medicare/Medicaid reimbursement rate (on average, at $110/a day in Michigan) does not fully cover hospice services, especially given the rise in costs of prescription drugs. This low rate precludes the use of any palliative chemotherapy or radiation, services that, in small doses, can ease pain if they are used to reduce (not eliminate) tumors. While the bills may encourage the Federal government to increase its reimbursement rates, they do not offer any concrete relief to hospices that provide services at a financial loss.

Legislative Analyst: Claire Layman

FISCAL IMPACT

Senate Bill 660

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

Senate Bills 661 & 662

Because the bills simply revise the type of information that must be contained in an insurance certificate, as opposed to mandating specific services, the bills should not have any fiscal impact on State or local government.

Senate Bill 781

Other than printing and distribution costs of an updated summary as required in the Act, this bill should result in no additional costs to State or local government.

Senate Bill 826

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

Senate Bill 827

According to the Department of Corrections (DOC) Statistical Report, in both 1998 and 1999, only one offender was convicted of

violating or attempting to violate MCL 333.7401 with regard to manufacturing, creating, delivering (or possessing with intent to manufacture, create, or deliver) an official prescription form. If one assumes that as in previous years, one offender will commit this offense but instead will be convicted for violating this section without the distinction of an "official" prescription form, and will receive the maximum sentence, which is seven years rather than 20, then the State will save $286,000. The maximum penal fine also is $5,000, instead of $25,000, which will decrease the amount of funds available for libraries.

The DOC Statistical Report also says that no offenders in 1998 or 1999 were convicted for violating MCL 333.7403 with regard to possessing either an official prescription form or prescription form. The bill eliminated the distinction between the two offenses, leaving one offense punishable as a misdemeanor with a maximum fine of $1,000, which will shift the responsibility for incarceration and probation costs from the State to local units of government and decrease the amount of funds available for libraries.

Repealing MCL 333.17766a, which prescribed penalties for androgenic anabolic steroid offenses, will have a minimal fiscal impact on State and local government. In 1998 and 1999, there was one offender per year convicted for violating this section. One received a fine, and the other was sentenced to a term of probation. Assuming past years are representative of the future, the bill will decrease criminal justice costs slightly as well as decrease the amount of funds available to libraries.

Senate Bill 828 and House Bill 5148

The bills will have an indeterminate impact on State government. The Secretary of State will have to redesign the layout of the personal identification card and the driver license to create a space for the decal.

Senate Bill 828 also eliminated the sunset on the $1 fee paid for the digitization of the personal ID cards. In FY 1999-2000, 276,535 personal ID card transactions were completed, generating $276,535 in revenue from this fee.

The bills will have no fiscal impact on local government.

House Bill 5255

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

House Bills 5258 & 5259

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

House Bills 5260 & 5261

These bills will require the Department of Consumer and Industry Services to create an electronic database to monitor prescriptions of Schedules 2, 3, 4, and 5 controlled substances. According to the Department, the creation of this system will cost approximately $1.3 million, which will be covered by the balance being transferred from the Official Prescription Form Program Fund to the new Pain Management Education and Controlled Substances Electronic Monitoring and Antidiversion Fund. The operation of the system is estimated to cost $1 million annually, which will be covered by the annual revenue already being collected from the $20 license fee. Therefore, there will be no real fiscal impact on the Department.

House Bills 5262 & 5263

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

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