House
Legislative
Analysis
Section

House Office Building, 9 South
Lansing, Michigan 48909
Phone: 517/373-6466

END OF LIFE CARE

House Bill 5148 as passed by the House
Sponsor: Rep. Jason Allen

House Bill 5255 as passed by the House
Sponsor: Rep. Artina Tinsley Hardman

House Bill 5256 as passed by the House
Sponsor: Rep. Randy Richardville

House Bill 5257 as passed by the House
Sponsor: Rep. Paula K. Zelenko

House Bill 5258 as passed by the House
Sponsor: Rep. Gene DeRossett

House Bill 5259 as passed by the House
Sponsor: Rep. Gary Woronchak

House Bill 5260 as passed by the House
Sponsor: Rep. Thomas M. George

House Bill 5261 as passed by the House
Sponsor: Rep. Paul N. DeWeese

House Bill 5262 as passed by the House
Sponsor: Rep. Stephen Ehardt

House Bill 5263 as passed by the House
Sponsor: Rep. Carl M. Williams

House Bill 5264 as passed by the House
Sponsor: Rep. Lauren Hager

House Bill 5265 as passed by the House
Sponsor: Rep. Andrew Raczkowski

House Bill 5266 as passed by the House
Sponsor: Rep. Michael C. Murphy

Second Analysis (11-16-01)
Committee: Health Policy

THE APPARENT PROBLEM:

Health care professionals and the general public tend to conceive of the ultimate purpose of health care in "curative" terms. In other words, people think that doctors and nurses are supposed to diagnosis medical problems and extirpate the cause of those problems at their source. In recent years, many health care professionals have stressed the need for the medical profession and the general public to acknowledge that there are some problems that medicine simply cannot solve. This is not primarily a function of the contemporary state of health care. Although there is good reason to believe that the art and science of medicine will progress in finding cures for individual ailments and diseases, there is equally good reason to believe that medicine will never reach the point at which it is capable of curing all ailments and diseases. In recognition of this ultimate "Achilles heel," which requires all human beings to confront their own mortality, medical professionals, as well as religious leaders and ethicists, have begun to focus heightened attention on the need to promote acceptance of "palliative" care as an essential component of high quality health care. Palliative care mitigates the symptoms or effects of a disease—pain, in particular—once health care professionals and their patients have come to terms with the difficulty or impracticability of finding a cure. In colloquial terms, if there is a problem, then doctors, pharmacists, and nurses should try to fix it; however, while they are trying to fix the problem, or if they come to the realization that they cannot fix it, they should at least try to alleviate the problem's effects. Although it may ultimately be less satisfying than care that cures a patient of his or her condition, palliative care may significantly enhance a patient's quality of life, when futile attempts to cure might give the patient a false sense of hope and prevent him or her from coming to terms with the condition.

Proponents of palliative care argue that effective pain and symptom management is important regardless of the specific ailment or disease. Nevertheless,

advocates are well aware that patients nearing the end of life have special needs. In June 1999, Governor Engler issued an executive order establishing the Michigan Commission on End of Life Care. Originally, the commission was to be composed of 17 members and was to complete its work within 15 months. In January 2000, however, the governor changed the number of members to 12 and extended the time frame for the commission's work. The commission's membership included doctors, nurses, social workers, administrators, lawyers, a professor of spirituality and ethics in medicine, a professor who serves as the director of a palliative care education and research program, two directors of state executive departments responsible for administering health care programs, and a state representative. In general, the commission was charged with identifying, compiling, and considering recommendations for improving end of life care from public and private organizations as well as making recommendations on the basis of its own discoveries.

Before it began its work, the members of the commission were well aware that attempts to promote high quality health care have wide-ranging effects throughout society. Advocating palliative care may seem like an indisputably worthy cause, in itself, but one of the primary means of effectively managing pain—the use of controlled substances—has always generated controversy. By definition, controlled substances have some potential to cause physical and/or psychological dependence, and even when they do not do so, they can significantly impair mental and bodily functioning. Although these undesired effects can largely be avoided through careful monitoring of the amount and dosage of medication and open dialogue regarding side effects, and a healthy doctor-patient relationship involves such monitoring and dialogue, such considerations ignore the widespread illicit use of controlled substances. Despite a marked tendency to focus on the abuse of drugs like heroin and LSD, whose distribution and consumption is strictly prohibited, Americans have increasingly come to realize that much drug abuse and misuse involves drugs that are available by prescription. This is true not just of drugs such as cocaine, whose legal use has long been overshadowed in the public's view by its illegal, recreational use, but also of drugs whose legitimate and illegitimate use are often less clearly distinguished, such as Demerol, Valium, Ritalin and Oxycontin. Some people who abuse or misuse these more commonly prescribed controlled substances are lured into a false sense of security by the very fact that they are so readily available by prescription. Disregarding the expertise of medical professionals who must make difficult judgments about the appropriateness of prescribing such substances, some abusers and misusers of prescription drugs wonder how dangerous they can be, given that they are (or seem to be) so widely prescribed. Add to this a small contingent of unscrupulous medical professionals who knowingly supply drugs to "doctor shoppers" and other abusers and misusers, and a small, but vocal minority of "conscientious objectors" to the "War on Drugs" who advocate the right to self-prescribe as integral to a truly free society, and the complexity of the controversy becomes clear.

Conceptually, the problem is how to promote the legitimate use of controlled substances, for controlling pain and other symptoms of disease and other medical conditions, without contributing to their illegitimate use. Historically, these issues came to the fore in Michigan during the 1980's. According to the Office of Substance Abuse of the Macomb County Department of Community Mental Health, Michigan became known as the "Miami of prescription drugs" in the 80's because prescription drug abuse had reached such epidemic proportions. In the latter part of the decade, the state legislature initiated what ultimately turned out to be a largely successful attempt to curb the diversion of those prescription drugs with the highest incidence of abuse and misuse—schedule 2 controlled substances. (See *BACKGROUND INFORMATION* for more information on controlled substances, in general, and schedule 2 controlled substances in particular.) After requiring that such prescriptions be written in triplicate and that one of the copies be forwarded to the state, Michigan virtually eliminated the problem of forged, fraudulent, and altered prescriptions for schedule 2 drugs. When it was revisited in the mid-1990's, the program came to be known as the Official Prescription Form Program (OPP) and was extended indefinitely. However, the triplicate prescription requirement was dropped in favor of a single-copy, serially numbered form and revised reporting requirements, which included revised requirements for allowing electronic reporting of prescription data to the state.

While taking heart in the OPP's successes, some people have expressed concern that focusing attention on schedule 2 controlled substances may lead to an unwelcome side-effect: an increase in the abuse and misuse of certain schedule 3, 4, and 5 drugs. (In 1997, the Controlled Substances Advisory Commission noted an increase in the availability of these other drugs, though it did not draw a causal connection between the OPP's focus on schedule 2 drugs and the increased use of drugs on other schedules.) Such abuse and misuse becomes all the more dangerous when it involves concoctions of narcotics and drugs like acetaminophen, whose misuse may lead to kidney and liver damage; Tylenol

#3 is an example of such a schedule 3 drug. Some people believe that an electronic system that effectively monitored the prescription of all controlled substances would provide authorities with additional means of eliminating their misuse use and abuse.

Having identified numerous barriers to quality end of life care ("EOL care") in the areas of professional education, pain management, consumer empowerment, and insurance and regulations, the commission presented its final report to the governor in August 2001. (See the report of the Department of Community Health web site, www.mdch.state.mi.us/eol/EOLreport.) Perhaps most controversially, the commission found that the Official Prescription Form Program, in its current form, impairs access to effective pain management without a corresponding benefit in the control of prescription drug diversion or quality of pain management. Many people have raised concerns with the program's primary focus on schedule 2 controlled substances, which they believe may lead to a shift in the misuse and abuse of other controlled substances available by prescription. Moreover, the "paper" reporting system makes it very difficult for anyone to assimilate data pertaining to prescriptions, and so it is unclear whether anyone really knows that certain aspects of the OPP are as successful as its defenders suggest. One particular area of controversy involves the state-issued form, currently required, and whether it is truly preventing forged, fraudulent, and altered prescriptions.

The commission also found problems with various references in statute and insurance policies to terminally ill patients. For instance, many people believe that the overall strategy of broadening acceptance of palliative care will only work if people accept the need for all individuals suffering from pain—not just those who are suffering from terminal diseases or "intractable" pain—to receive treatment. Moreover, the commission argued that hospice care may be underutilized not only because insurers frequently restrict coverage to patients with a six month life expectancy or less, but also because patients and physicians are not sufficiently educated about hospice care. Many practitioners who do know about hospice care are reluctant to refer patients too early in the progression of a patient's condition. Finally, the commission reported that physicians and patients are not effectively communicating about—and that patients do not have sufficient means for implementing—certain "tools" for planning for the end of life that are already available, such as advance directives and do-not-resuscitate orders.

Legislation has been proposed based in part on the commission's recommendations. However, the package of legislation reflects not only the work of the Michigan Commission on End of Life Care, but also the input of members of a workgroup consisting of various other members of the health care profession and industry who were not members of the commission, and the suggestions of the Health Policy committee and those who attended committee meetings.

THE CONTENT OF THE BILLS:

House Bills 5255-5256 were introduced as part of an "End of Life Care" package. The package also includes House Bill 5254, which remains under consideration by the Committee on Tax Policy at this time. House Bill 5148 was introduced before the package but also deals with end of life issues. Specifically, the bills would do the following:

House Bill 5259. Article 17 of the Public Health Code regulates health care facilities and agencies. Among other things, the article requires a health facility or agency that is licensed under the article, and that provides services directly to patients or residents, to adopt a policy describing the rights and responsibilities of patients and residents who are admitted to the facility or agency.

House Bill 5259 would amend this article (MCL 333.20201) to require such a policy to recognize that 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. The bill would also revise various references to a "health facility or agency" to clarify which provisions applied to health facilities or agencies, generally, and which provisions applied to specific types of health facilities or agencies, such as nursing homes and homes for the aged. Further, the bill would clarify that a licensed health maintenance organization must comply with the Insurance Code of 1956 rather than with a section of the Public Health Code repealed in 1997. Finally, the bill would update certain references to the federal Social Security Act.

House Bills 5255 and 5256. House Bills 5255 and 5256 would amend requirements regarding information hospitals and nursing homes must provide patients concerning hospice care and palliative care services.

House Bill 5255. Part 215 of the Public Health Code provides for the licensing and regulation of hospitals. House Bill 5255 would amend this part of the code (MCL 333.21534) to specify that, upon the request of a patient, a hospital would have to provide patients

with oral and written information on hospice care and palliative care services and the availability of hospice care in the area. A patient's physician, a member of the patient's family, the patient's designated patient advocate, or the patient's legal guardian would be authorized to request—and would have to be provided with—the information as well.

House Bill 5256. Part 217 of the Public Health Code provides for the licensing and regulation of nursing homes. Among other things, the code requires a nursing home to execute a written contract with an applicant or patient at the time an individual is admitted to a nursing home and at the expiration of the term of a previous contract. Alternatively, a nursing home may execute a written contract with the applicant's or the patient's guardian or legal representative who is authorized by law to have access to those portions of the patient's or applicant's income or assets available to pay for nursing home care. House Bill 5256 would amend this part of the code (MCL 333.21766) to add a requirement that a nursing home notify applicants or patients of the availability of hospice care in the nursing home before executing the written contract.

Specifically, the bill would require that the nursing home provide written notification to a patient or applicant or his or her guardian or legal representative of the availability or lack of availability of hospice care in the nursing home. The written notice would have to be provided in a specific paragraph located in the written contract, and that paragraph would have to be signed or initialed by the applicant, patient, guardian, or representative before the execution of the written contract.

Currently, the written contract must specify the term of the contract and the services, and charges for services, to be provided under the contract, among other things. The bill would state that the contract's specification of services (and charges for services) to be provided under the contract had to indicate the availability of hospice or other special care. The bill would also require that the written contract specify the ability of the patient or the patient's guardian or legal representative to void the contract under specific circumstances.

"Hospice" would mean "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."

House Bills 5257 and 5258. The Michigan Dignified Death Act, which is Part 56a of the Public Health Code, contains various references to "terminal illness" and "terminally ill patients." "Terminal illness" is 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." House Bill 5258 would amend the Michigan Dignified Death Act (MCL 333.5652 et al.) to change references to "terminally ill" patients to patients who "have a reduced life expectancy due to an advanced illness." The bill would also revise certain provisions that specify what information physicians must provide to such patients. House Bill 5257 would revise a requirement that the Department of Community Health develop and publish a standardized, written summary containing information specified in a provision that would be amended by House Bill 5258. The bills are tie-barred. Specifically the bills would do the following:

House Bill 5258 would eliminate the definition of "terminal illness" from the Michigan Dignified Death Act altogether. The act currently contains a statement of the legislature's findings with respect to terminally ill patients, and the bill would revise several of these findings so that they referred to "patients having a reduced life expectancy due to an advanced illness" rather than to "terminally ill patients." The bill would also add the legislature's finding that health care providers should be encouraged to discuss medical directives during initial consultations, annual examinations, and hospitalizations, as well as when a patient is diagnosed with a chronic illness and when a patient transfers from one health care setting to another. One finding that would retain a reference to "terminal illness" currently acknowledges that patients face a unique set of circumstances and decisions once they have been diagnosed as having a terminal illness. The bill would, however, revise this finding to state that patients who had been diagnosed as having a terminal *or advanced* illness face a unique set of circumstances and decisions. The bill would also specify that it should not be construed as creating a new mandated benefit for any coverage issued under the Insurance Code of 1956, the Nonprofit Health Care Corporation Reform Act, or any other health care payment or benefits plan. Changes specific to the act's information requirements are summarized below.

Requirements that physicians orally inform patients of certain options. Currently the act requires a physician to provide certain information to a patient (or representative) when recommending medical treatment for a patient who *has been diagnosed* as having a terminal illness. (The act also allows the physician to inform the patient's surrogate or the patient's designated advocate of the patient's options, in the event that the patient is unable to participate in

medical treatment decisions.) Specifically, the act requires the physician to orally inform the patient (or other representative) about the *recommended medical* treatment for the illness and about alternatives to the *recommended medical* treatment. The physician must also orally inform the patient about the advantages, disadvantages, and risks of the recommended medical treatment and each alternative medical treatment. House Bill 5258 would make the following changes to these requirements. To begin with, the bill would require a physician *who had diagnosed a patient* as *having a reduced life expectancy due to an advanced illness* and was recommending medical treatment for the patient to inform the patient of his or her options. This reflects two basic changes. First, the bill would refer to a physician who had diagnosed a patient as opposed to a physician who had been diagnosed, and second the bill would refer to a patient having a reduced life expectancy due to an advanced illness rather than a patient with a terminal illness. The bill would also require the physician to inform a patient (or representative) orally about medical treatment for the illness and about *alternatives to medical treatment* for the illness. The bill would, however, continue to require the physician to orally inform the patient about the advantages, disadvantages, and risks of the medical treatment and of each *alternative medical treatment.* (The bill would not explicitly require a physician to inform the patient about the advantages, disadvantages, and risks of *alternatives to medical treatment.*)

Requirements that physicians inform patients of certain options both orally and in writing. The act specifies further information that a physician must provide to a patient (or representative) whom the physician has diagnosed as having a terminal illness and for whom the physician is recommending medical treatment. In general, this further information must be provided to the patient both orally and in writing. The bill would add a requirement that a physician inform a patient whom he or she had diagnosed as having a reduced life expectancy due to an advanced illness, both orally and in writing, that the patient may choose adequate and appropriate pain and symptom management as a basic and essential element of medical treatment.

House Bill 5257. House Bill 5257 would amend the Michigan Dignified Death Act (MCL 333.5656 et al.) to change references to "terminally ill" patients to patients who "have a reduced life expectancy due to an advanced illness." As described above, the act currently requires—and House Bill 5258 would continue to require—that a physician provide certain information to a patient both orally and in writing. The act originally required the Department of Community of Health to develop and publish a written summary containing this information by the end of May 1997, allowing a physician to give patients a copy of the summary instead of notifying them of their options both orally and in writing. House Bill 5257 would require the department to develop and publish a new summary containing the revised information that a physician must provide to a patient both orally and in writing. The new report would have to be developed and published by January 1, 2002. The bill would continue to allow a physician to give a patient a copy of the department's summary instead of notifying the patient of his or her options orally and in writing.

Effective dates. The changes allowing a physician to provide a patient with a copy of the department's written summary instead of informing the patient both orally and in writing (House Bill 5257) and the changes to the information requirements—oral only and oral and written—(House Bill 5258) would take effect on March 1, 2002. The other changes to the act would take effect on the bills' effective date.

House Bills 5260 - 5262. Article 7 of the Public Health Code regulates controlled substances and, among other things, provides for an "official prescription form program," or "OPP." Article 15 of the code regulates health care occupations, and the general provisions of Article 15 set forth several legislative findings and directives concerning the OPP, controlled substances, and the treatment of "intractable" pain. Among other things, the general provisions of Article 15 state that the OPP "was created to prevent the abuse and diversion of controlled substances included in schedule 2 . . . and not to prevent or inhibit the legitimate, medically recognized use of those controlled substances to treat patients with cases of intractable pain, especially long-term treatment. It is the intent of the legislature to permit and facilitate adequate treatment for intractable pain by licensed health professionals, including, but not limited to, the prescription or dispensing of controlled substances included in schedule 2 . . ., when medically appropriate."

House Bills 5260 - 5262 would amend various provisions in Articles 7 and 15 of the Public Health Code. House Bill 5260 would replace the official prescription form program for schedule 2 controlled substances with an electronic reporting system for the prescription of all controlled substances. House Bill 5261 would amend Article 15 to abolish the Official Prescription Form Program Fund and create a Controlled Substances Electronic Monitoring Fund and a Pain Management Education and Controlled Substances Antidiversion Fund. House Bill 5262 would revise several definitions relating to

prescriptions in the general provisions of Article 7; these revisions include a requirement that prescriptions for controlled substances and other prescription drugs be written on secure, tamper-resistant material. House Bills 5260 and 5262 are tie-barred to one another; House Bill 5261 is tie-barred to the other two bills.

House Bill 5260 would amend Articles 7 and 15 of the Public Health Code (MCL 333.7333 et al.) to eliminate the official prescription form program. The bill would replace a statement providing explicit justification for creating the OPP with a statement that the legislature intended, in addition to permitting and facilitating adequate pain management, to enable regulatory and law enforcement agencies to prevent the abuse and diversion of controlled substances by creating an electronic monitoring system. The bill would eliminate references to the official prescription form and the OPP throughout Articles 7 and 15 and would provide for an electronic system for monitoring schedule 2, 3, 4, and 5 controlled substances. The bill would also eliminate a definition of "intractable pain" and various references to intractable pain in the general provisions of Article 15. Finally, the bill would eliminate a definition of and references to "androgenic anabolic steroids." (Certain anabolic steroids are now included on the list of schedule 3 drugs provided in an administrative rule, R 338.3122, promulgated by the Department of Community Health. Other anabolic steroids are excluded from schedule 3 or excluded from the schedules altogether, as set forth in the rule.)

Electronic reporting system. The Department of Consumer and Industry Services would have to establish, by rule, an electronic system for monitoring schedule 2, 3, 4, and 5 controlled substances that were dispensed in the state by veterinarians, pharmacists, and dispensing "prescribers" or that were dispensed to an address in the state by a pharmacy licensed in the state. CIS would require a veterinarian, pharmacist, or prescribing dispenser to utilize the electronic data transmittal process developed by CIS's contractor. The rules would have to provide an appropriate electronic format for the reporting of data including patient identifiers, the name of the controlled substance dispensed, the date of dispensing, the quantity dispensed, the prescriber, and the dispenser. A veterinarian, pharmacist, or prescribing dispenser would not have to pay a new fee dedicated to the operation of the system, nor would he or she be responsible for any additional costs for transmitting data to CIS. The bill would specify that the rules would exempt from the reporting requirements the administration of a controlled substance directly to a patient. Moreover, a prescriber dispensing a controlled substance in a quantity adequate to treat a patient for up to 48 hours from a licensed health facility or agency would be exempt from the reporting requirements. Otherwise, reporting would be mandatory for a pharmacist, veterinarian, and dispensing prescriber. However, the department could issue a written waiver for use of the electronic system to any pharmacist, veterinarian, or dispensing prescriber who established grounds that he or she was unable to use the electronic system. The department would require the applicant for the waiver to report the required information in a manner approved by the department.

Forgery-resistant paper form. CIS would be required to examine the need for and could promulgate rules for the production of a prescription form on paper that minimized the potential for forgery, in consultation with the Controlled Substances Advisory Commission, the Michigan Board of Pharmacy, the Michigan Board of Medicine, the Michigan Board of Osteopathic Medicine and Surgery, and appropriate medical professional associations. The rules could not include any requirement that sequential numbers, bar codes, or symbols be affixed, printed, or written on a prescription form or that the prescription form be a state produced prescription form. In examining the need for rules for a paper, forgery-resistant prescription form, CIS would have to consider and identify the costs, benefits, and barriers of such a form, an overall cost-benefit analysis, and the form's compatibility with the electronic monitoring system. The department would have to report its findings to the members of the House and Senate standing committees having jurisdiction over health policy issues at least 120 days before the electronic monitoring system became operational.

Sharing data. CIS could provide data to all of the following: a designated representative of a board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other person who was authorized to prescribe, administer, or dispense controlled substances and who was involved in a bona fide specific investigation involving a designated person; a state, federal, or municipal officer whose duty was to enforce state or federal laws relating to drugs and who was engaged in a bona fide specific investigation involving a designated person; a state-operated Medicaid program; a properly convened grand jury pursuant to a properly issued subpoena for the records; a practitioner or pharmacist who requested information and certified that the requested information was for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient. The bill would also specify that a person who received data or any report containing any patient identifiers of the system from the department could not provide it to

any other person or entity except by order of a court of competent jurisdiction. The Controlled Substances Advisory Commission would have to include in its annual report, as provided for elsewhere in Article 7, information on the implementation and effectiveness of the system. The department, all law enforcement officers, all officers of the court, and all regulatory agencies and officers, in using data for investigative or prosecution purposes, would have to consider the nature of the prescriber's and dispenser's practice and the condition for which the patient was being treated. The data and any report containing any patient identifiers obtained from the data would not be a public record and would not be subject to the Freedom of Information Act.

Schedule 2 controlled substances. Currently, the code prohibits, with some exceptions, the dispensing of a schedule 2 controlled substance or an androgenic anabolic steroid without the written prescription of a licensed practitioner. The prescription must be written on an official prescription form. The bill would change this qualified prohibition to specify only that a schedule 2 controlled substance could not be dispensed without the prescription of a licensed practitioner on a "prescription form." (See below House Bill 5262's proposed revision to the code's definition of "prescription form.") The bill would also prohibit a practitioner from issuing more than one prescription for a schedule 2 controlled substance on a single form. Further, the bill would change the period during which a prescription for a schedule 2 controlled substance had to be filled from five to sixty days from the prescription's issuance; this provision currently does not apply—and still would not apply—to terminally ill patients whose terminal illness was documented by the pharmacist. Finally, the bill would eliminate a prohibition on the refilling of prescriptions for a schedule 2 controlled substance or for an androgenic anabolic steroid, other than methyltestosterone, testosterone, or fluoxymensterone.

Schedule 3 or 4 controlled substances. Currently a prescription for a schedule 3 or 4 controlled substance may not be filled or refilled later than six months after the date of the prescription or be refilled more than five times, unless renewed by the *practitioner* in accordance with rules promulgated by the Michigan Board of Pharmacy or its designated or established authority. The bill would state that a prescription for schedule 3 or schedule 4 controlled substances could not be filled or refilled more than five times in that time frame, unless renewed by the "prescriber." (See below the definition of "prescriber" that would be added by House Bill 5262.)

Expansion of provision specific to written prescriptions. In general, controlled substances must be prescribed in writing, but the code does provide for cases in which a prescriber may need to prescribe a controlled substance orally—e.g., emergency situations. Currently, the code requires that a prescription that must be written must contain the quantity of the controlled substance or androgenic anabolic steroid prescribed, in both written and numerical terms. The bill would state instead that if a prescription was required, the prescription would have to contain the quantity of the controlled substance prescribed in both written and numerical terms.

Postdating prescription forms. Currently, the code prohibits a prescribing practitioner from postdating an official prescription form or from signing an official prescription form on a day other than the day the prescription is issued. The bill would eliminate these references to the official prescription form and specify instead that a prescribing practitioner could not postdate a prescription form that contained a prescription for a controlled substance. A prescriber could transmit a prescription by facsimile and by electronic transmission of a printed prescription form, as long as it was not prohibited by federal law. If a prescription was electronically transmitted, it would be transmitted directly to the pharmacy, and the data could not be altered, modified, extracted, viewed, or manipulated in the transmission process.

Transition period. The bill provides for the repeal of certain provisions of Article 7 and Article 15 as soon as the department promulgated the rules for the electronic monitoring system *and* the secretary of state received written notice from the director of CIS that the system was operational. The notice to the secretary of state would have to include a statement that CIS was able to receive data from at least 80 percent of those required to report and was able to respond to requests for data from persons authorized to make such requests and to review and utilize the data. The changes to Article 7 would take effect at the same time as the repeals. Other changes would take place on the bill's effective date.

House Bill 5261 would amend Article 15 of the Public Health Code (MCL 333.16315) to abolish the Official Prescription Form Program Fund and create a Controlled Substances Electronic Monitoring Fund and a Pain Management Education and Controlled Substances Antidiversion Fund. The bill would create both funds within the state treasury, and the treasurer would be responsible for directing the investment of both funds. Interest and earnings from the investment of each fund would be credited to that fund, and the unencumbered balance in each fund at

the close of the fiscal year would remain in that fund rather than reverting to the general fund. Each fund could receive gifts and devises and other money as provided by law.

The Controlled Substances Electronic Monitoring Fund. The state treasurer would be directed to transfer the money remaining in the Official Prescription Form Program Fund on the bill's effective date to the Controlled Substances Electronic Monitoring Fund. The department of treasury could only use the fund in connection with developing and maintaining the electronic monitoring system.

The Pain Management Education and Controlled Substances Antidiversion Fund. Currently, the law states that the Department of Consumer and Industry Services is to deposit with the state treasurer $20 of the fee for a license to engage in manufacturing, distributing, prescribing, dispensing, or conducting research on controlled substances. The treasurer is directed to credit the $20 (per license fee) to the Official Prescription Form Program Fund. The bill would direct the treasurer to deposit the $20 to the Pain Management Education and Controlled Substances Antidiversion Fund instead. The department could only used this fund 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.

House Bill 5262 would amend Article 7 of the Public Health Code (MCL 333.7104 et al.) to revise several definitions. To begin with, the bill would eliminate the definition of "official prescription form," in conjunction with House Bill 5260's elimination of the OPP, and modify the definition of "prescription form." The law currently defines a prescription form as a printed form that was authorized and intended for use by a prescribing practitioner to prescribe controlled substances or prescription drugs. The bill would retain the current requirement that the prescription form meet requirements of rules promulgated by the Michigan Board of Pharmacy or its designated or established authority. Further, the bill would add requirements that a prescription form do all of the following: bear the preprinted, stamped, typed, or manually printed name, address, and telephone number or pager number of the prescribing practitioner; include 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 registration number; state the quantity of the prescription drug prescribed in both written and numerical terms; and include the date the prescription drug was prescribed. Further, the prescription form would also have to conform to any rules promulgated by CIS concerning the forgery-resistant form described above.

The bill would also add a definition of "sign," meaning to affix one's signature manually to a document or to use an "electronic signature." An "electronic signature" would mean 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, the bill would incorporate a definition of "prescriber" by reference to the part of Article 15 that regulates occupations involving pharmacy practice and drug control. (As defined in that part, "prescriber" means "a licensed dentist, a licensed doctor of medicine, a licensed doctor of osteopathic medicine and surgery, a licensed doctor of podiatric medicine and surgery, a licensed optometrist certified . . . to administer and prescribe therapeutic pharmaceutical agents, a licensed veterinarian, or another licensed health professional acting under the delegation and using, recording, or otherwise indicating the name of the delegating licensed doctor of medicine or licensed doctor of osteopathic medicine and surgery.") Finally, the bill would revise the definition of "counterfeit prescription form" by eliminating reference to the official prescription form and recognizing as counterfeit a prescription form that had been electronically transmitted without the prescriber's knowledge or permission.

Transition period. The changes would take effect as soon as the department promulgated the rules for the electronic monitoring system *and* the secretary of state received written notice from the director of CIS that the electronic monitoring system was operational. As described for House Bill 5260, the director of CIS would have notify the secretary of state that CIS was able to receive data from at least 80 percent of those required to report and was able to respond to requests for data from persons authorized to make such requests and to review and utilize the data.

House Bills 5263-5265. House Bills 5263-5265 would amend provisions of the Public Health Code, the Insurance Code of 1956, and the Nonprofit Health Care Corporation Reform Act, to eliminate definitions of and references to "intractable" pain. Specifically, the bills would do the following:

House Bill 5263. Among other things, Article 15 of the Public Health Code provides for the creation of a committee with certain responsibilities regarding pain and symptom management. The bill sets forth requirements for the composition of the committee, including a requirement that the committee include

one registered professional nurse, one dentist, one pharmacist and one physician's assistant, all of whom must have training in the treatment of "intractable" pain. House Bill 5263 would amend Article 15 (MCL 333.16204a) to eliminate the requirement that these four members have training in the treatment of intractable pain, specifying instead that they had to have been trained in the treatment of pain.

House Bill 5264. Chapter 34 of the Insurance Code regulates disability insurance policies and Chapter 36 of the code regulates group blanket disability insurance policies and family expense insurance policies. Chapter 22 of the code currently requires that an insurer that delivers, issues for delivery, or renews in this state an expense-incurred hospital, medical, or surgical policy or certificate issued under Chapters 34 or 36 provide a written form to an insured person upon enrollment. The form must describe the terms and conditions of the insurer's policies and certificates. Currently, the form must describe how the covered benefits apply in the evaluation and treatment of "intractable" pain, among other things. House Bill 5264 would eliminate the reference to intractable pain, specifying instead that the form had to describe how the covered benefits apply in the evaluation and treatment of pain. The bill would also eliminate the reference to intractable pain in a provision that allows individuals covered by such policies or certificates to request a description of the professional credentials of participating health professionals, including those who are board certified in the evaluation and treatment of intractable pain. Instead, a covered insured could request information on the professional credentials of participating health care professionals, including those who were board certified in the evaluation and treatment of pain.

House Bill 5265. The Nonprofit Health Care Corporation Reform Act requires, among other things, that a health care corporation provide a written form to subscribers upon enrollment that describes the terms and conditions of the corporation's certificate. Like the form described above, this form must describe how the covered benefits apply in the evaluation and treatment of "intractable" pain. House Bill 5265 would eliminate this reference to intractable pain, specifying instead that the form had to describe how the covered benefits applied in the evaluation and treatment of pain. Like House Bill 5264, the bill would also revise a provision that allows members for certain offered services to request a description of the professional credentials of participating health professionals, including those who are board certified in the evaluation and treatment of intractable pain. Instead, members could request a description of the professional credentials of participating health professionals, including those who were board certified in the evaluation and treatment of pain. Finally, the bill would specify that it was not to be construed as creating a new benefit for any coverage issued under the Nonprofit Health Care Corporation Reform Act.

House Bills 5148 and 5266. House Bills 5148 and 5266 would amend requirements for driver's licenses and state personal identification cards to allow them to indicate certain preferences with regard to emergency medical information and end of life care issues.

House Bill 5148. The Michigan Vehicle Code charges the secretary of state with issuing operator's and chauffeur's licenses (i.e., driver's licenses) to qualified applicants. House Bill 5148 would amend the vehicle code (MCL 257.310) to allow a license to contain a statement that the licensee carried an emergency medical information card or to contain a sticker or decal indicating that the licensee had designated a patient advocate. The emergency medical information card could contain the licensee's emergency contact information, information concerning the licensee's patient advocate designation, other emergency medical information, or an indication as to where the licensee had stored or registered emergency medical information.

The sticker or decal indicating that the licensee had designated one or more patient advocates, in accordance with the Estates and Protected Individuals Code, would have to meet the secretary of state's specifications. Any person, hospital, school, medical group, or association interested in assisting in implementing the emergency medical information card could provide the sticker or decal.

House Bill 5266. Public Act 222 of 1972 allows an individual who does not have a valid operator's or chauffeur's license to apply for a state personal identification card, whose form is prescribed by the secretary of state. Currently, the act specifies that an applicant must pay the secretary of state a $6 fee for each original or renewal state identification card plus a $1 service fee. However, the $1 service fee is scheduled to be eliminated on January 1, 2002.

House Bill 5266 would amend the law (MCL 28.292) to require that the secretary of state designate a space on the card where the applicant could place a sticker or decal of a uniform size—determined by the secretary of state—to indicate that the cardholder carried a *separate* emergency medical information card. The sticker or decal could also be used to indicate that the cardholder had designated one or more patient advocates, in accordance with the

Estates and Protected Individuals Code. Any person, hospital, school, medical group, or association interested in assisting in implementing the emergency medical information card could provide the sticker or decal, but the sticker or decal would have to meet the secretary of state's specifications. The (separate) emergency medical information card could contain certain information pertinent to an individual's indication of willingness to have his or her name placed on the organ donor registry and information concerning the licensee's patient advocate designation. It could also contain other emergency medical information or an indication as to where the cardholder had stored or registered emergency medical information. The bill would also eliminate the January 1, 2002 "sunset date" for the $1 service fee for the state identification card; thus, the $1 itself would become a permanent addition to the $6 fee for the original or renewal card.

BACKGROUND INFORMATION:

Controlled substances. Following federal law, the Public Health Code classifies controlled substances under one of five "schedules." By definition, all scheduled drugs have the potential for abuse, where the abuse is "associated with" a stimulant or depressive effect on the central nervous system. Further, scheduled drugs 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 that have a potential for psychological or physical dependence (schedules 2, 3, 4, and 5). Schedule 1 and schedules 2 drugs are both defined as having a "high risk" of abuse, and drugs on schedule 3-5 have successively reduced potential for leading to dependence. In other words, schedule 3 drugs have a lower risk of causing dependence than schedule 2 drugs, schedule 4 drugs have a lower risk of leading to dependence than schedule 3 drugs, and schedule 5 drugs have a lower risk of leading to dependence than schedule 4 drugs. Alternatively, a drug may be placed on schedule 5 if "the incidence of abuse is such that the substance should be dispensed by a practitioner."

Schedule 2 prescription drugs. Drugs included on schedule 2 include opium and its derivatives, (e.g., codeine, morphine, and oxycodone, which is the active ingredient of Oxycontin), opium poppy and straw, other opiates (e.g., fentanyl, methadone, and pethidine), coca leaves and derivatives, such as cocaine, and methylphenidate—the active ingredient of Ritalin. Schedule 2 also includes substances containing any quantity of such drugs as amphetamine and methamphetamine (also known as "speed"), methaqualone (known by its trade name Quaalude), and barbiturates, such as amobarbital, pentobarbital, and secobarbital (a.k.a. "downers").

Schedule 3, 4, and 5 prescription drugs. 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 (known by its brand name Valium), barbital, chloral hydrate, lorazepam, meprobamate, and phenobarbital. Loperamide (Imodium AD) is an example of a Schedule 5 drug.

Governor's charge to the Michigan Commission on End of Life Care. The governor's June 1999 executive order charged the Michigan Commission on End of Life Care with the following nine responsibilities:

- Identifying, compiling, and considering recommendations for improving end of life care from the state's public and private organizations;

- Recommending model state and institutional policies with respect to end of life care, including an examination and compilation of the best ideas of multiple groups currently engaged in examining end of life issues;

- Coordinating their efforts with other groups actively engaged in addressing end of life issues;

- Identifying, evaluating, and making recommendations with respect to any existing barriers that result in inadequate end of life care;

- Evaluating the adequacy of, and making recommendations for improving, education associated with end of life care provided in medical schools, nursing schools, and other health professional education programs;

- Evaluating the adequacy of the level and degree of, and making recommendations for improving, graduate medical education training provided in residency programs associated with end of life care;

- Surveying the availability and cost of public and private insurance coverage for hospice, pain management, and palliative care (see Appendix B of the report);

- Recommending state policies concerning end of life care related to continuing medical education for licensed health professionals; and

- Inventorying existing resources available to citizens for end of life planning and producing a guide of

these resources for the general public (see the summary of Appendix C below).

Appendix C: Barriers to end-of-life care. In the course of its study, the commission determined that barriers to providing appropriate EOL care stem primarily from limited resources, shortcomings in the health care system, and society's difficulties in dealing with end of life issues. Although there are many barriers to appropriate EOL care, the commission focused its discussion of barriers that need to be addressed and eliminated around four themes: professional education, pain management, consumer empowerment, and insurance and regulations.

Professional education barriers. Barriers in the area of professional education include: lack of professional training and continuing education of health care professionals in diagnosing and treating patients with life-threatening conditions and identifying when a condition or illness is nearing the terminal stage; failure to offer patients both curative and palliative choices; lack of competency and experience in compassionate dialogue with patients and families in EOL care issues; and lack of understanding of basic patient rights of informed consent, including the right to accept or reject specific types of care.

Pain management barriers. Barriers in the area of pain management include: lack of knowledge on the part of clinicians and patients that patients have a right to have their pain assessed, treated, and relieved; lack of understanding by patients of how to communicate pain (and the appropriateness of doing so; lack of knowledge by professionals of how to elicit and measure patients' reports of pain and pain relief; lack of knowledge of the full range of pharmacologic and nonpharmacologic pain treatments; and inadequate understanding of the side effects of pain medication and misconceptions concerning potential addiction. Specific to health care providers, the commission found the following barriers: insufficient education in palliative care, insufficient knowledge about symptoms of the end of life other than pain, frequent failure to conform to current standards and clinical practice guidelines for pain assessment and relief, and fear of regulatory scrutiny for prescribing controlled substances, among other things.

Consumer empowerment barriers. In the area of consumer empowerment, the commission determined that the single most significant barrier is the lack of education in EOL issues such as patient rights, advance directives, designation of surrogates for EOL decision-making, and the options for treatment, including hospice and palliative care. Further, the commission found that patients often lack access to palliative care specialists, do not understand the relationship between curative and palliative care, and do not know that pain and symptoms can be managed without foregoing all options for curative care. Finally, the commission found that physicians fail to present all options to patients and that physicians and surrogates often did not sufficiently understand patients' goals and preferences.

Insurance and regulations barriers. Among the many barriers to reimbursement, the commission emphasized the lack of—or gaps in—insurance coverage for some EOL services based on current models of care and today's finances, the inadequacy of hospice reimbursement for palliative care, and eligibility restrictions for appropriate but expensive therapies. The commission noted special concern with Medicare's requirement that coverage of hospice care begin after a prognosis of six months or less of life remaining, which is ultimately based on cancer research, as opposed to research on a wide variety of "terminal" illnesses. Regulatory issues include the limitations of EOL care for terminally ill patients in state mental hospitals, limitations on EOL care treatment options placed on providers by MCO's, inadequate dissemination of available knowledge by payors on EOL issues, and the absence of processes designed to encourage the beneficiary to keep advance directives current. Quality assurance issues include lack of consistent reporting of EOL care data, lack of benchmarks for measuring and evaluating patient quality-of-care outcomes near the end of life, and lack of consistency in standards of care across the continuum.

Recommendations. Having identified the barriers to quality end of life care, the commission issued four general recommendations: (1) the governor and legislature should adopt several specific principles for formulating public policy for end of life care; (2) the governor, the Department of Community Health (MDCH), and the Department of Consumer and Industry Services (CIS) should initiate a statewide awareness and educational campaign for the public and for health care professionals; (3) the MDCH should nurture an ongoing coalition of public and private stakeholders to reshape health care delivery systems to provide appropriate and competent curative and palliative care services; and (4) the MDCH and CIS should develop public policy and draft regulations for EOL care based on standards developed by experts in the field in order to promote competent and appropriate care for Michigan residents living and dying with advanced illness.

The committee also issued a number of specific recommendations, including: three recommendations in the area of professional education, twelve recommendations on pain and symptom management, five concerning reimbursement, two regarding long-term care, four with respect to end of life decision-making, and one recommendation on family issues. With respect to family issues, the commission specifically recommended that, in the interest of promoting the health and well-being of Michigan citizens, the governor and MDCH encourage provision of competent respite care to reduce caregiver burden and encourage health plans and other payors to provide adequate reimbursement for such service. The other specific recommendations are listed below in the order that they appear in the report's "executive summary of recommendations," except that recommendations for legislative action that directly relate to bills in the End of Life Care package have been moved to the top of the list, within each category.

Professional education recommendations. In the area of professional education, the commission recommended that:

1. Health professional schools or educational programs include in their core curricula content on EOL care appropriate to each discipline. More specifically they should:

- Charge at least one faculty member with developing the curriculum.

- Regularly assess and evaluate curriculum content, consider the professional expertise of faculty involved in EOL care education, support faculty development, and draw on the experience of community professionals.

- Collaborate with other schools within each discipline and within the larger educational institution to enhance instruction in EOL care.

- Develop new models of education that incorporate adult learning principles and interactive learning to improve the abilities of health care professionals as they care for dying persons.

2. MDCH take a leadership role in exploring options for EOL care education innovation grants to support curriculum assessment, development, and evaluation by individual schools and educational programs; and for development of interdisciplinary and inter-institutional efforts to improve EOL education.

3. MDCH, CIS, and all applicable health profession licensing boards promote and advance the art and science of EOL care education and promote palliative care as a defined area of expertise, education, and research.

Pain and symptom management recommendations. In the area of pain and symptom management the commission recommended that:

1. The legislature repeal the OPP because in its current form the OPP impairs access to effective pain management without a corresponding benefit in the control of prescription drug diversion or quality of pain management. (See House Bills 5260-5262.)

2. The legislature replace the OPP with a system that supports electronic monitoring; is balanced in its approach to high-quality pain management and its desire to limit prescription drug diversion; requires no additional special prescription form; is efficient and invisible to the patient and practitioner; and provides information that is well understood and available to all those who need it. (See House Bills 5260-5262.)

3. The legislature amend the Michigan Dignified Death Act to eliminate the terminology "life expectancy of less than six months" and replace it with language to require physicians who identify a patient with limited life expectancy due to advanced illness to provide the patient with information about pain and symptom management options. (See House Bills 5257 and 5258.)

4. The legislature amend the "Policy on Patient and Resident Rights and Responsibilities" within the Public Health Code stating that all patients have the right to adequate pain and symptom management and palliative and hospice care. (See House Bill 5259.)

5. The legislature amend all statutes to eliminate the use of the term "intractable pain" or amend it to read "pain" as appropriate. (See House Bills 5263-5265.)

6. The legislature, MDCH, and CIS minimize state regulatory impediments to effective pain medications and work with the Michigan Congressional delegation and federal officials to minimize federal regulatory impediments concerning prescriptions.

7. CIS adopt licensing requirements for health facilities and agencies that promote education programs for health professionals on effective pain and symptom management.

8. CIS and MDCH adopt by regulation and monitor the progress of licensed health facilities and agencies in implementing the Joint Commission on Accreditation of Healthcare Organizations' (JCAHO)

pain treatment requirements in order to improve individual and timely assessment and treatment of pain.

9. All applicable health profession licensing boards adopt and disseminate the Federation of State Medical Boards' "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain" and adopt policy declaring that inappropriate undertreatment of pain will be scrutinized.

10. CIS develop a system and promulgate rules that require pharmacies to help patients find adequate supplies of pain medications when the pharmacy is unable fill a valid prescription.

11. MDCH and the Office of Financial and Insurance Services (OFIS) encourage health plans and payors to minimize co-pays, deductibles, and other restrictions on reimbursement for opioids prescribed for pain and symptom management.

12. MDCH, CIS and the Department of Environmental Quality (DEQ) explore ways to improve disposition of pharmaceuticals when no longer required for home use—e.g., requiring that in settings that have a central point of control, unused pharmaceuticals be retrieved and redistributed to other patients with legitimate prescriptions.

Reimbursement recommendations. In the area of reimbursement, the commission recommended that:

1. MDCH assess and validate existing state data to determine how to optimize EOL care by analyzing, redistributing, and redesigning incentives in order to provide more options concerning type and settings of care.

2. The governor, MDCH, and CIS work with the Michigan Congressional delegation and federal agencies to further understand and explore current or proposed federal laws and regulations for Medicare and Medicaid to determine their impact and make changes in the following areas:

- Development of an "outlier" formula for large-scale hospice programs whose patients need higher-cost services or require services in settings where significant transportation costs exist.

- Development of an acuity-based reimbursement formula for the first and last days in hospice in light of the rapidly declining length of stay, which creates an increasing proportion of high-cost days.

- Amending the twenty percent limit on inpatient hospice days in relation to total hospice days for programs that can document service to a disproportionately large number of high-acuity patients.

- Modifying the Medicare hospice benefit by creating a financially neutral reimbursement methodology for nursing home hospice care so that Medicare beneficiaries may choose hospice care without penalty to the nursing home or eligible residents.

- Reimbursing palliative care providers as appropriate to meet patients' and families' EOL care needs.

3. MDCH review the final report of the Hospice Residence Research Project to determine if funding the room-and-board component of inpatient hospice residences is a cost-neutral means of delivering patient care.

4. The legislature encourage and consider funding research projects designed to evaluate the hypothesis that offering both curative and palliative services concurrently is cost-effective.

5. Health plans and payors be encouraged to pay the reasonable cost of pain and symptom management, palliative care consultations, and non-pharmacological treatment of pain and symptoms by all types of providers.

Long-term care recommendations. In the area of long-term care, the commission recommended that:

1. CIS and the Michigan Long Term Care Work Group (LTCWG), together with providers of long-term care, continue to address barriers that interfere with the deliver of quality EOL care, including:

- Confusion and conflict concerning the interpretation and enforcement of regulations dealing with avoidable and unavoidable decline and the reluctance to use medications that are perceived to interfere with function—e.g., psychotropic or opiate medications—for terminally ill patients.

- Lack of adequate pain and symptom management.

- A focus on restorative and rehabilitative care as opposed to palliative care or comfort care.

- Disincentives for long-term care facilities to offer hospice and palliative services to residents.

- Absence of best-practice models for palliative EOL care within long-term care settings.

2. CIS and the LTCWG develop educational and training opportunities in EOL care for state surveyors of long-term care facilities, particularly on issues concerning avoidable and unavoidable decline related to the naturalness of dying.

Decision-making for the end of life. In the area of decision-making for the end of life, the commission recommended that:

1. The Michigan Dignified Death Act be amended to provide that regardless of whether a patient is terminally ill, physicians should engage in discussions about advance directives during initial consultations, periodic examinations, in-hospital consultations upon admission to or transfer from one health care setting to another, and at diagnosis of a chronic illness. (See House Bill 5258.) In conjunction with this recommendation, the commission recommended that:

- Studies be conducted to determine the best practices for involving physicians in effective discussions with patients about advance directives and actual implementation of advance directives.

- Managed care organizations, health plans, and other payors be encouraged to include medical-record documentation of physicians' discussions with patients as a quality indicator for physician practice.

2. Driver's licenses and other identification cards clearly denote when a person has executed a do-not-resuscitate order and whether a person has an advance directive (and where it can be found). (See House Bills 5148 and 5266.)

3. The state court administrator's office take a leadership role in seeing that courts, court personnel, guardians *ad litem*, and others are well prepared to administer, enforce, and provide education about the guardianship reform laws passed in 2000.

4. The MDCH director establish a working group of advocates, interested parties, and health care professionals to work toward assessing the numerous issues associated with EOL decision-making for persons who have never been competent and who are terminally ill.

"End of Life Care package". In October 2001, an "End of Life Care" package, consisting of seven resolutions and thirteen bills, was introduced in the House. The resolutions and twelve of the bills, House Bills 5255-5266, were referred to the Health Policy committee. House Bill 5254, which would amend the General Sales Tax Act, was referred to the Tax Policy committee and remains under consideration by that committee at this time. Although House Bill 5148 had been introduced earlier in the month, and thus was not introduced under the auspices of the End of Life Care package, it deals with the same issues covered by House Bill 5266, and thus falls within the general rubric of end of life care legislation. For the purposes of this analysis, the "End of Life Care package" (or "EOL package") refers to House Bills 5148 and 5255-5266. (On October 30, House Bills 5256 (Substitute H-1), 5259, and 5263-5265 were passed by the House.)

Even a fairly close examination of the bills composing the EOL package might not make obvious the bills' focus on end of life care issues. Indeed, the bills seem to cluster around several conceptual themes, which might be arranged from least clearly related to end of life care issues to most clearly specific to such issues, as follows: pain and symptom management (in general); requirements relating to the prescription of controlled substances; the accessibility of information concerning end of life care (e.g., advance directives, the designation of patient advocates, and emergency medical information); the treatment of patients with a reduced life expectancy due to an advanced illness; and hospice care. Undergirding this broad thematic spectrum, however, lies the prehistory of other legislative attempts to address such complexly interwoven phenomena as patterns of drug abuse and misuse, perceptions about the proper goal(s) of medicine, attitudes about death and dying, notions of individual autonomy and societal and familial obligations. Two significant episodes in this prehistory are the implementation of what eventually came to be known as the Official Prescription Form Program (OPP) and Michigan's confrontation with the reality of assisted suicide.

History of the Official Prescription Form Program

Michigan in the 1980's. During the 1980's, Michigan ranked first in the nation in the consumption of several schedule 2 prescription drugs, which have recognized medical uses, for which they may be prescribed legally, but are considered the most highly addictive of the controlled substances. In 1983, for example, Michigan reportedly received 35 percent of the methamphetamine consumed in the United States. In the same year, the state was also the top consumer of Ritalin, Preludin, and Dilaudid. After two years of special enforcement activity and revised rules, the consumption in Michigan of certain schedule 2 drugs, such as methamphetamine and phenmetrazine (Preludin), dropped considerably, but consumption of other schedule 2 drugs remained high. Reportedly, many of the drugs were "diverted" from legal channels to illegal and abusive distribution channels through forged and stolen prescription pads and forms; dishonest doctors, pseudo-doctors, and

pharmacists who prescribed and/or dispensed the drugs for illegitimate purposes; and duped, troubled, and out-of-date practitioners who wrote prescriptions for "doctor shoppers" and other abusing patients. A 1989 pharmacist survey estimated that approximately 104,000 forged and/or altered prescriptions for schedule 2 drugs were presented to pharmacists annually.

Public Act 60 of 1988. In 1987, legislation was introduced by the Senate to address these and related problems. Enacted as Public Act 60 of 1988, the law created a Controlled Substances Advisory Commission and required the use of triplicate prescription forms for the dispensing of certain controlled substances, among other things.

Controlled Substances Advisory Commission. The Controlled Substances Advisory Commission ("CSAC") was—and still is—required to monitor indicators of controlled substance abuse and diversion. The CSAC was originally housed in the Department of Licensing and Regulation, but is now located within the Department of Consumer and Industry Services. If the data shows that the state exceeds the national average per capita consumption of a controlled substance, the CSAC must investigate and determine whether there is a legitimate reason for the excess consumption. If it determines that there is not a legitimate reason for the excess consumption, the CSAC must recommend a plan of action for overcoming the problem to the drug control administrator appointed by the Michigan Board of Pharmacy. It may also recommend action if other indicators show that a special problem is developing with any controlled substance available by prescription.

CSAC annual report. The CSAC was—and still is—required to issue an annual report on the current status of the abuse and diversion of controlled substances in the state, and the report must identify existing efforts to overcome that abuse and diversion and make recommendations for needed legislative, administrative, and interagency activities. The CSAC may also include recommendations for action involving licensing, law enforcement, substance abuse treatment and prevention, education, professional associations, pharmaceutical manufacturers, and other relevant individuals and agencies.

Official triplicate prescription ("trip scrip") form program. Prior to the enactment of Public Act 60 of 1988, the law stated merely that a schedule 2 controlled substance could not be dispensed without the written prescription of a licensed practitioner. (Exceptions were made for emergencies, as long as the prescription was promptly put into writing and filed by the dispensing pharmacy.) In general, Public Act 60 of 1988 required that prescriptions for schedule 2 substances be written on an official prescription form and prohibited the recording of more than one prescription on a single form. An "official prescription form" was defined as a prescription form that was numbered serially, was in triplicate, and contained 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 federal Drug Enforcement Administration (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 ultimate user's "authorized agent," if any.

A person who prescribed schedule 2 controlled substances was required to fill in all three copies of the prescription form and include all of the information listed above, except the name, address, and DEA number of the dispensing pharmacy and the pharmacist's initials. The prescriber had to sign and give the first two copies to the patient, and the prescriber had to retain the third copy for at least five years from the date that the prescription was written. The pharmacist had to record the pharmacy information on the two copies of the prescription that the prescriber gave to the patient. The pharmacist had to keep the second copy on record for at least five years and had to sign and send the first copy to the department by the 15th of the month following the month it was written. The pharmacist was also required to transmit to the department a copy of each prescription for a schedule 2 controlled substance issued by a practitioner residing in a state that borders Michigan, whose practice extended into Michigan but had no office in the state. Alternatively, the pharmacist could send a document that contained the required information.

The law prohibited a prescriber from using a prescription form for a purpose other than prescribing. It also prohibited a prescriber from postdating a form or from signing a form on a date other than the date indicated on the form. A person in possession of prescription forms issued by the department whose license to dispense or practice, or whose DEA number had been suspended or revoked, was required to return to the department all unused prescirption forms within seven days of the suspension or revocation.

The law contained special provisions for emergency situations and controlled substance analogues (synthetic, "designer" drugs that have a chemical

structure and effects on the central nervous system that are substantially similar to controlled substances), as well as provisions setting forth penalties for violations and ensuring confidentiality protection. The law also required the department and commission to submit a report to the legislature on the effectiveness of the triplicate prescription program by October 1, 1993.

CSAC's April 1993 evaluation report and PA 138 of 1993. According to the Controlled Substances Advisory Commission's April 1993 evaluation of the triplicate prescription program, the state-issued prescription forms for schedule 2 drugs virtually eliminated the problem of schedule 2 drug diversion. This judgment was corroborated by the federal Drug Enforcement Administration, the Michigan Department of State Police, and the Michigan Board of Pharmacy, among others. The commission's evaluation report recommended a number of changes to the program, several of which were incorporated in Public Act 138 of 1993.

Specifically, the legislation extended the Official Prescription Form Program, but replaced the triplicate form, required for schedule 2 drug prescriptions, with a single-copy prescription form, effective January 1, 1995. The prescribing practitioner was required to give the single sheet form to the patient, which had to contain the same information as was required on the first copy of the triplicate prescription form. Moreover, he or she had to enter the name of the schedule 2 drug, the dosage, and the quantity prescribed, as well as the instructions for its use in the patient's record. When the pharmacist received the official prescription form, he or she had to forward the form to the department or transmit the information electronically or on storage media. The Department of Commerce was required to develop a standardized data base format for transmitting information electronically or on storage media by the end of 1993; the data base format had to be consistent with the standards of the National Council for Prescription Drug Programs (NCPDP). (This was actually a revision of a provision in Public Act 60 of 1988 that had required the CSAC to develop a standardized database format for transmitting such information electronically or on storage media by August 1, 1990. The CSAC had complied with this requirement, but the format was not required to be, and was not, consistent with the NCPDP standards.) If the pharmacist sent the (paper) form to the department, he or she had to retain a copy of the form.

The act also dropped methylphenidate (Ritalin) from the OPP. (According to the 1997 evaluation report, methylphenidate comprised over 50 percent of submitted prescription forms at the time. Also, Michigan ranked first in the nation for the prescription and distribution of Ritalin, with statewide distribution of the drug at an estimated 200 percent of the national average.)

1997 OPP evaluation report. The 1993 legislation that extended the Official Prescription Form Program 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; and the use of the single copy official prescription form; and any changes the department recommended be made in the program. In September 1997, the Department of Consumer and Industry Services (formerly the Department of Commerce) submitted its report, which was prepared by the Office of Health Services in conjunction with the CSAC; the report contained several important findings. First, the OPP had continued the reduction in the number of prescriptions and units prescribed for the three most diverted schedule 2 medications prior to implementation of the triplicate prescription program; the three drugs were oxycodone (Percodan), meperidine (Demerol), and hydromorphone (Dilaudid). This data was corroborated by data collected independently by federal government agencies. Second, there was an increase in the number of prescriptions submitted to the OPP from 1990 to 1996 (adjusted for the removal of methylphenidate from the OPP), reflected primarily in the increase of prescriptions for morphine, fentanyl, and dextroamphetamine. Morphine and fentanyl are prescribed primarily for chronic pain, and dextroamphetamine, like Ritalin, is commonly prescribed for Attention Deficit Disorder (ADD). Third, 1996 pharmacist and prescriber surveys suggested that the OPP was achieving the legislated goal of reducing the diversion of schedule 2 drugs and that the monitoring of schedule 2 drug prescriptions had no "chilling effect" on prescribers' selection of appropriate drug therapy. Approximately two-thirds of prescriber survey respondents agreed or strongly agreed that the OPP was not preventing them from providing schedule 2 medication that patients needed; thirteen percent of respondents disagreed or strongly disagreed.

The report also confirmed the CSAC's 1993 finding that the triplicate prescription program had virtually eliminated the problem of forged, fraudulent, and altered prescriptions for schedule 2 drugs. However,

the Office of Health Services and CSAC did find that the distribution of schedule 3, schedule 4, and schedule 5 drugs had increased significantly. Law enforcement and treatment officials identified hydrocodone and codeine *combination drugs*, in particular, as the most often sought prescription drugs for illicit purposes. (Although hydrocodone and codeine are schedule 2 drugs in "pure" form, mixtures containing hydrocodone and codeine as ingredients may appear on schedule 3, 4, or 5 depending on the concentration of the schedule 2 drug in the mixture. Vicodin is a well-known, and much abused, hydrocodone combination drug, whereas Tylenol #3 and #4 are codeine concoctions.) According to the Michigan State Police Diversion Investigation Unit, schedule 3, 4, and 5 drugs, which do not require an official prescription form, were often obtained through forged, fraudulent, and altered prescriptions. The report did not explicitly draw a causal connection between the success of the OPP in virtually eliminating of diverted prescriptions for schedule 2 drugs and the increase in diverted prescriptions for schedule 3, 4, and 5 drugs. The CSAC reviewed the information relative to the schedule 3, 4, and 5 drugs and discussed the possibility of adding those drugs to the OPP, but ultimately decided not to do so. As reasons for its decision, the CSAC cited the large volume of schedule 3, 4, and 5 drug prescriptions and the fact that schedule 3 through 5 drugs may have refills, whereas schedule 2 drugs may not have refills.

The report also found: (1) the OPP was a cost-effective means of eliminating forged schedule 2 prescriptions; (2) the electronic transmission of official prescription form data reduced handling time and did not increase cost; and (3) the new single form was widely accepted by both prescribers and pharmacists.

The full report with appendices is available on line at the Department of Consumer and Industry Services web site: www.cis.state.mi.us/bhser/opp.

Assisted suicide and pain management

Assisted suicide and the Michigan Commission on Death and Dying. On June 4, 1990 the nation and the state were forced to enter the protracted, heated controversy over assisted suicide, when it was reported that Dr. Jack Kevorkian helped Oregon resident Janet Adkins to die in northern Oakland County. However much they may have rehearsed the moral arguments, Michiganians found themselves improvising on center stage, having discovered that state law neither explicitly prohibited nor explicitly permitted the practice. When they enacted P.A. 270 of 1992, state legislators created the crime of "criminal assistance to suicide" and established the Michigan Commission on Death and Dying (MCDD), charged with developing recommendations on legislation regarding "voluntary self-termination of life." The law's constitutionality was challenged in the courts, but even after the state supreme court ultimately ruled that it was constitutional, the debate over assisted suicide raged on.

The MCDD held meetings, heard testimony, and collected information, and it became increasingly clear that consensus on the issue of whether it was appropriate to ban assisted suicide would not be achieved. The MCDD did, however, note widespread support for the opinion that the medical community was inadequately addressing the needs of patients experiencing acute or chronic pain, regardless of whether they were terminally ill. Reportedly, emerging pain and symptom management therapies—particularly those involving controlled substances—remained underutilized, despite their availability and effectiveness. Several explanations were given for underprescription, including that doctors were not properly educated in pain management techniques and that doctors feared litigation from patients or their advocates who believed that patients were being overmedicated. Moreover, the MCDD also heard that prescribers feared the intense scrutiny of regulatory authorities who, they believed, overzealously monitored the prescription of schedule 2 controlled substances. In conjunction with the expressed need for pain and symptom management for the terminally ill, many people believed that the increased use of hospice care should be promoted.

The MCDD's final "report". Because the members of the MCDD could not agree on what the legal status of assisted suicide should be, its final "report" actually included three minority position reports, each articulating one of the primary positions that emerged from the debate. Despite this lack of agreement on the preferred legal status of assisted suicide, the MCDD did reach consensus on a number of related points. One key point in the consensus was that "*some permanent policy regarding assisted suicide should be enacted by the Legislature* (emphasis in the report)." This was all the more relevant since the 1992 law criminalizing assisted suicide provided for its own repeal, effective six months after the date that the MCDD made its recommendations. The "report" stated emphatically: "[*t*]*he Commission views the current situation, whereby the ban on assisting a suicide is scheduled to sunset six months after this report, as untenable* (emphasis in original)." Having taken up the debate the MCDD thought it would be irresponsible to revert to not having a law regarding assisted suicide.

Whether the MCDD's final "report" satisfied the act's reporting requirement—and thus, whether the act was effectively repealed six months after the document was submitted—remains unclear. The House of Representatives formally received the commission's "report" on June 21, 1994. The Senate, however, did not formally receive the commission's "report."

In its "report," the commission issued several recommendations, which are perhaps more relevant for understanding the "prehistory" of the End of Life Care package. Proponents and opponents of assisted suicide agree that people ought not feel pressured into taking their own lives and that the medical profession should do everything it can to ensure that approaching the end of life is not characterized by a significant, preventable decline in the quality of life. To refine patients' understanding of issues concerning death and dying, the MCDD recommended that the legislature provide for public education about advance health care directives, patients' control over their medical treatment and their obligations towards others with respect to medical treatment, and patients' right to treatment for pain and other distressing symptoms. The commission also recommended that the legislature take action to do the following: (1) augment suicide prevention initiatives; (2) ensure the referral of individuals inquiring about self-termination to experts who may be able to assist the individual in acquiring services and supports that would alleviate the individual's suffering; (3) encourage the development of model core curricula and continuing education on pain and symptom management, physician-patient partnerships, and treatment options for people with disabilities or chronic or terminal illnesses for medical personnel and students; (4) ensure that initial licensure exams for health care professionals include an evaluation of their knowledge of issues listed under (3); (5) modify the use of triplicate prescriptions for those with a terminal illness and/or severe pain; (6) improve access to palliative care including hospice care; (7) enact health care reform proposals including access to programs and support services which may provide alternatives to self-termination; and (8) provide education for health care professionals and the general public through partnerships with professional organizations, in pain and symptom management, the use of palliative care and hospice care, and the limitations of medical treatment and the viability of comfort care.

Public Acts 232-236 of 1994. Public Acts 232-236 of 1994 were enacted largely as an attempt to implement the commission's various recommendations on the issues of assisted suicide, hospice care, and pain management. The acts established an interdisciplinary advisory committee to advise licensing boards on education for health professionals on pain and symptom management. The acts also required such education for the licensure and renewal of licensure of certain health professionals and mandated that various health insurers offer to provide hospice care coverage and inform those they insured about the coverage.

The Michigan Dignified Death Act. The MCDD 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. Significantly, the MCDD found that competent patients have the right to refuse medical treatment and the right to the treatment of pain and other symptoms of a disease, even if such refusal or treatment unintentionally hastens or increases the risk of the patient's death. These findings provided the background for the 1996 enactment of the Michigan Dignified Death Act. The act required that physicians inform "terminally ill" patients of alternative medical treatments, palliative care (including hospice services), and their rights to designate a patient advocate and to 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 such a prescription. "Terminal illness" was—and still is—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."

A version of the Michigan Dignified Death Act passed by the Senate would have included a requirement that a physician inform a terminally ill patient under his or her care that it was illegal, under Michigan law, for the physician or anyone else to assist the patient to commit suicide. As enrolled, the act dropped this requirement.

Pain management and Public Acts 421-426 of 1998. Discussions about assisted suicide throughout the 90's revealed, and focused attention on, the fact that the medical community often provided inadequate treatment not just for terminally ill patients, but for all patients suffering from chronic pain. Pain specialists had been warning the profession about the undertreatment of pain for over 25 years. Statistics estimated that 34 million people in the U.S. suffered from chronic pain, and one quarter of all sick days were used for pain, resulting in billions of dollars in lost wages annually. A survey conducted by the

Michigan Council on Pain, created in 1995, showed that one in five adults in Michigan live with chronic pain. According to a 1996 poll, however, "[d]espite its immense cost to the American economy, and independent of the suffering and loss of quality of life that it brings, business, government, and insurers have not offered a systematic approach to the treatment of this high cost, . . . nor have credentialed systems of care been made available to most patients who require it."

In addition, anecdotal testimony given in hearings conducted around the state suggested the following: individuals with chronic pain were being given insufficient quantities or dosages of pain medication; doctors refused to accept chronic pain sufferers as patients; emergency room physicians refused treatment of people with severe pain or refused to prescribe narcotic drugs to control the pain; health maintenance organizations (HMOs) and other managed care plans made it difficult for individuals to receive referrals to pain specialists; insurers denied payment for certain drugs or pain treatments. Yet, many individuals reported that when given sufficient quantities of pain medication in appropriate dosages, they were able to return to work and engage more fully in social and family life.

Among other things, Public Acts 421-426 of 1998 revised the composition and duties of the Advisory Committee on Pain and Symptom Management and required insurance companies and HMO's to clearly indicate how covered benefits would apply in the evaluation and treatment of "intractable pain." Intractable pain was defined as "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. . . ." Among the changes to the committee were requirements that the committee include persons trained in the treatment of intractable pain and a person who was diagnosed as suffering from chronic pain. The acts also articulated statements of legislative intent related to intractable pain and provided for certain reporting requirements and educational activities with respect to pain and symptom management. One of the central statements of legislative intent was that the Official Prescription Program had been created to prevent the abuse and diversion of schedule 2 controlled substances and not to prevent or inhibit the legitimate, medically recognized use of those drugs to treat patients with cases of intractable pain. The legislature also intended to permit and facilitate adequate treatment for intractable pain by licensed health professionals, which would include dispensing schedule 2 drugs when medically appropriate.

KASPER. Proponents of the expansion of electronically reporting prescription data find hope in the apparent success of the Kentucky All Schedule Prescription Electronic Reporting program ("KASPER"). In response to 1998 state legislation, the Kentucky Cabinet for Health Services implemented KASPER, which, as its name suggests, is a schedule 2-5 controlled substance electronic prescription monitoring and reporting program. (Drugs included on individual schedules may be different in Kentucky.) KASPER requires all pharmacies, except inpatient hospital pharmacies, dispensing physicians, dispensing veterinarians, or other licensed dispensers of schedule 2, 3, 4, and 5 drugs to complete and submit a record of each prescription to the same private contractor. All such records must be submitted within sixteen days of the date of dispensing, which means that pharmacies and other dispensers must submit them at least twice a month. Moreover, the pharmacy or dispenser must submit the records electronically—e.g., on diskette, magnetic tape, or by modem—unless the pharmacy or dispenser has received a waiver from electronic reporting, in which case the pharmacy or dispenser may use a standard universal claim form or another approved paper report. A pharmacy or dispenser must submit a form indicating that no prescriptions for schedule 2-5 drugs were prescribed, if that is the case. For nursing homes, prescriptions for "skilled" or "intermediate care" patients do not have to be reported, but prescriptions for personal care patients, Hospice patients, employees, or other outpatients must be reported. For hospitals, any outpatient prescription dispensed by the hospital pharmacy must be reported, but inpatient prescriptions dispensed do not have to be reported. (This information, some of which was prepared by the private contractor, is available at the Kentucky Department of Public Health's Branch of Drug Control web site: publichealth.state.ky.us/drug_control.htm. Some of the details provided may reflect how the program has been administered and implemented rather than the actual legislative requirements.)

FISCAL IMPLICATIONS:

According to the House Fiscal Agency, House Bills 5148, 5255, 5256, 5258, 5259, and 5263 - 5265 would have no fiscal impact on either the state or on local units of government, and House Bill 5257 would have a negligible fiscal impact on the state or on local units of government. (10-23-01 and 11-13-01)

The House Fiscal Agency reports that House Bills 5260-5262 would have no impact on state revenues but would have an indeterminate impact on state costs. Regarding the impact on state costs, the move from the OPP to the electronic monitoring system would result in one-time transition costs, paid for by the newly created Controlled Substances Electronic Monitoring Fund, which would be funded by the unrestricted balance remaining in the Official Prescription Form Program Fund. CIS estimates that much of this money could be needed to finance start-up costs for the new system. In terms of the annual operating costs of the new system, the state would save money currently used to meet printing and distribution costs under the OPP, but the proposed monitoring of schedule 3, 4, and 5 controlled substances—in addition to schedule 2 controlled substances that are currently monitored—would increase costs. CIS estimates that these new savings and new costs would offset one another. However, the $20 of each controlled substance licensing fee paid by manufacturers, distributors, prescribers, dispensers, and researchers of controlled substances, which currently goes into the Official Prescription Form Program Fund, would be deposited in the new Pain Management Education and Controlled Substances Antidiversion Fund. Money in this fund could be used for the maintenance of the new electronic monitoring system, but would also be used to support pain management education for health professionals and preventing the diversion of controlled substances. Since much of the money from the Controlled Substances Electronic Monitoring Fund would go to the start-up costs of the new system, it is not clear how much, if any, of the money from the Pain Management Education and Controlled Substances Antidiversion Fund would be available to support pain management education and antidiversion efforts. Further, if program costs themselves outpaced the supporting fee revenue, another funding source such as general fund revenues would have to be tapped. (11-16-01)

The House Fiscal Agency reports that House Bill 5148 could require the secretary of state to reformat operator's and chauffeur's licenses to accommodate a label, decal, or statement, and the cost projection for reformatting the licenses is indeterminate at this time. (10-24-01)

The House Fiscal Agency reports that House Bill 5266 would require a one-time reformatting of the state personal identification card, costing no more than $10,000. By continuing to charge the $1.00 service fee, the bill would result in an increase in state revenues of approximately $250,000 annually, though the fiscal year 2002 increase would only be approximately $187,500. (10-30-01)

ARGUMENTS:

For:

In the area of consumer empowerment, the commission found that "[t]he biggest single barrier is lack of education in end-of-life issues such as 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 acknowledges that often patients "do not understand the relationship between curative and palliative care or know that pain and symptoms can be managed without forgoing all options for curative care." House Bill 5258 would "encourage" physicians to discuss advance directives with patients during initial consultations, periodic examinations, in-hospital consultations upon admission to or transfer from one health care setting to another, and at diagnosis of a chronic illness. Moreover, it would require a physician who had diagnosed a patient as having a reduced life expectancy due to an advanced illness and was recommending treatment for the patient would have to inform the patient of his or her right to choose adequate and appropriate pain and symptom management as a basic and essential element of medical treatment. Also, House Bill 5255 would allow a hospital patient or authorized representative of a hospital patient to request and receive information regarding hospice and palliative care services and information on the availability of hospice care in the area in which the hospital was located. The bills all recognize the need for patients to make—and for medical facilities and personnel to encourage—informed decisions, and thus go a long way toward eliminating the barrier identified by the commission.

Response:

The commission's report stresses the need for educating both the public and professionals about hospice and palliative care services, but patients often enter their doctors' offices thinking that "the doctor knows best" and waiting to take his or her cues. Unfortunately, neither of the bills would require a physician or hospital to initiate discussion about advance directives, the patient's right to adequate and appropriate pain and symptom management, or hospice and other palliative care services. The commission's report acknowledges as a (perceived) barrier professionals' "lack of competency and experience in compassionate dialogue with patients and families on end-of-life issues." Despite their present lack of experience, more of the burden of initiating conversations on such difficult topics should be placed on health care professionals. Health care providers should be *required*—not merely encouraged—to discuss medical directives with patients. Likewise, physicians should be required to

inform their patients of their right to adequate and appropriate pain and symptom management orally as well as in writing; although House Bill 5258 appears to do this, House Bill 5257 would allow a physician to give a patient a copy of a written summary, which states that the patient has this right, but includes other information as well. Even a patient who read and understood the material might be disinclined to initiate a conversation regarding hospice or palliative care. If a health care provider has not taken the time or effort to "reach out" to the patient verbally, the patient may worry that requesting such services involves a tacit admission that he or she has simply "given up." In short, a hospital should be required to notify a patient of the availability of hospice care in the hospital, and health care providers should be required to initiate conversations regarding EOL care services with their patients.

For:

House Bill 5256 would require nursing homes to notify prospective patients of the availability of hospice care at the nursing home. Nursing homes have an obligation to keep patients—whether present or prospective—apprised of end of life care issues and options. Many patients who are nearing the end of the life do not take advantage of hospice care early enough for such care to make a significant difference in their "quality of life." Part of the problem arises from the fact that Medicare patients, for instance, are only eligible for hospice care coverage if they are certified as terminally ill and as having a life expectancy of less than six months, and doctors may be hesitant to diagnose a patient as having such a short life expectancy. (Blue Cross and Blue Shield of Michigan and Medicaid have similar time specifications, though they allow for extensions.) Still, a major problem is that patients simply do not know enough about hospice care. People entering nursing homes should be encouraged to become more knowledgeable about end of life care options and issues, and the availability of hospice care could be a significant factor in a patient's decision about whether to enter a specific nursing home. Also, a patient who knows that hospice care is an available option and a doctor who knows that a patient knows about hospice care may find it easier to broach the subject of end of life care issues.

Further, as passed by the House, the bill improves upon its original form. As introduced, the bill would have allowed a patient to render the contract void if he or she had not been informed prior to signing the contract that hospice care was (or was not) available. The requirement that information about the availability of hospice care be included in the contract was designed to encourage patients to think ahead and to facilitate discussions between patients and their health care providers. Explicitly permitting a patient to render the contract void detracted from the bill's focus on the need to promote thinking and talking about end of life care issues.

Response:

It is extremely important that nursing homes inform applicants and patients of the availability of hospice care, and in addition to encouraging thinking ahead and facilitating discussion of options, the bill should provide some strong protection for nursing home patients who are not informed that hospice care is unavailable. The possibility that a patient who has not been properly notified of the availability or unavailability of hospice care might render the contract void—as would have been allowed under the bill as it was introduced—would provide nursing homes with a significant incentive to comply with the bill's requirements. Moreover, it makes good sense that a patient who signed a contract for services with a nursing home that failed to comply with statutorily mandated contract specifications should be allowed to opt out of the contract.

For:

House Bills 5258 and 5259 would reaffirm a patient's basic right to palliative care that is well-established in state and federal law. House Bills 5260 – 5262 would create a new electronic reporting system for monitoring the prescription of all controlled substances available by prescription. The Public Health Code and the Federal Controlled Substances Act attempt to strike a balance between a patient's right to safe and effective drugs for legitimate medical purposes including pain management, on the one hand, and the public's interest in detecting and preventing the diversion of prescription drugs for illegal use, on the other. Despite widespread misconceptions about palliative care, experts agree that early, aggressive pain and symptom management generally lengthens and improves the quality of patient's lives. In its report to the governor, however, the Michigan Commission on End of Life Care decried the lack of effective pain and symptom management in the state as "a public health issue that requires the highest level of professional and regulatory attention." The commission identified the current Official Prescription Form Program as a significant barrier to the delivery of adequate, appropriate treatment of pain, suggesting that the OPP has focused its attention on the diversion of schedule 2 controlled substances to the detriment of patients who have legitimate need for pain medication. The OPP, in the words of the commission, "perpetuates an unbalanced systemic approach to the use of opioids as controlled substances in Michigan. The rules and regulations promulgated by the OPP impair Michigan citizens'

access to effective pain management without providing the intended corresponding benefit of controlling the diversion of prescription drugs for inappropriate non-medical use." Only eight cases of prescription drug diversion occurred in the state in 2000, yet "fewer than one-third of the state's most severely ill and dying patients . . . presented with their pain adequately managed." Experts in the field of pain and symptom management have long warned of the "chilling effect" that the current focus on schedule 2 drugs has on doctors who fear the intense scrutiny of state regulators and law enforcement officials, and 40 percent of physicians who responded to the commission's survey reported that they feared such scrutiny. Some doctors even indicated that they prescribe medications on other schedules even when they are known to be less effective or could have serious side effects—e.g., cause damage to the stomach, liver, and kidneys.

Moreover, the commission suggested that the OPP "has little effect . . . on detecting and preventing drug diversion." Currently, the state-issued paper prescription form must be taken to, or forwarded to, the pharmacy, which can then either send the form to CIS or transmit the information contained on the form electronically or on storage media. Since many pharmacists already do transmit the information on the form electronically—as opposed to sending the form itself—CIS rarely sees the state-issued forms after they have been issued. Thus, pharmacists, not the state, are primarily the ones who detect signs that prescriptions have been tampered with, and do so in a fairly haphazard way. Furthermore, paper is gradually becoming regarded as an obsolete means of recording and storing data. However much it staggers the mind to conceive of the reams of paper prescription forms that must have accumulated over the years, it is yet more unfathomable to imagine the drudgery involved in trying to transform such unwieldy data into a readily assimilable and manipulable form. Thus, even if CIS were collecting all the official prescription forms, it would probably not be able to effectively use the information to reduce the number of forged, fraudulent, and altered prescriptions. In short, it is hardly clear that the OPP, in its current form, is successfully eliminating—or could successfully eliminate—the diversion of controlled substances that are available by prescription, and the only real support for the OPP's alleged benefits does not justify the costs to patients who lack adequate treatment for their pain.

By monitoring all controlled substances available by prescription electronically and by making data available to legitimate investigators, state regulatory agencies, law enforcement agencies, and other investigators, authorities will be able to more easily track dispensing patterns and follow up on shifting trends in the distribution of such drugs. The bills would make great strides in restoring the balance between the individual patient's need for appropriate and adequate pain management and law enforcement authorities' and regulators desire to prevent the abuse and diversion of controlled substances on behalf of the general public.

Finally, House Bills 5260 and 5262 prudently direct CIS, in consultation with the Controlled Substances Advisory Commission, the Michigan Board of Pharmacy, the Michigan Board of Medicine and Surgery, and the appropriate medical professional associations, to examine the controversial issue of whether the state should require prescribers to use a paper prescription form that minimizes the potential for forgery. According to some people, requiring prescribers to use a state-issued form or another specific type of form would greatly restrict their ability to prescribe when and where they need to do so. Since prescribers might not always have such forms handy, requiring such forms could delay the delivery of pain treatment in some cases. Proponents of state-issued forms or other types of secure, tamper-resistant forms, on the other hand, believe that they are essential to a prescription monitoring program that is designed to maintain a low incidence of drug diversion. Moreover, they argue that prescribers may currently, and would continue to be able to, phone in prescriptions in emergency situations, where immediate delivery of pain treatment is necessary. Since there is considerable controversy on this issue and since the bills would allow for a transition period from the current system to the new system anyway, it makes sense to have CIS examine the need for a "forgery-resistant" prescription form.

Response:

House Bill 5260 expressly directs CIS to consider the need for a forgery-resistant form. However, the Detroit Field Division of the federal Drug Enforcement Administration and the Michigan Pharmacist Association believe that the prescription form must be tamper-resistant if the new program is going to prevent forged, fraudulent, and adulterated prescriptions. Further, the bill prohibits CIS from requiring a state-issued form or a form that used sequential numbers, bar codes, or symbols that were affixed, printed, or written on the form, despite the fact that some people believe that such requirements are necessary. The Michigan Association of Substance Abuse Coordinating Agencies, for instance, believes that without a state-issued form the state may well find itself saddled with the widespread street availability of prescription drugs, as it was in the early 1980's. In short, the bills fail to strike the necessary balance between the patient's right to safe and effective drugs for legitimate medical purposes

and the public's interest in detecting and preventing the diversion of prescription drugs for illegal use. The heated controversy over the specifications of a paper prescription form indicate, at the very least, that the legislature should set forth requirements in statute.

Reply:

Any legislation, including both the current OPP and the proposed electronic system, that requires that the state be notified when controlled substances are prescribed risks causing some prescribers to write fewer controlled substance prescriptions or to write prescriptions for weaker controlled substances, due to their fear of regulators' scrutiny. The vast majority of prescribers share the desire to reduce drug diversion, but requiring a special "forgery-resistant" form, let alone a state-issued form, would sacrifice the interest in promoting appropriate, adequate care.

For:

House Bills 5260 and 5263-5265 would revise certain references to "intractable pain" to refer to "pain" only. The focus in current law on pain that is "intractable" seems to suggest that some forms of pain are more *worthy* of being treated than other forms of pain. Pain is an elusive and irreducibly subjective phenomenon, which has befuddled some philosophers enough to try to solve rarified epistemological conundra such as whether two people can ever be assured that they mean the same thing when they say that they are in pain. Doctors and dentists employ clear, proven techniques for determining whether patients have broken bones or cavities. When they ask their patients how badly their broken bones and cavities hurt though, they resort to asking patient's questions such as, "on a scale of one to ten, how bad is the pain?" Based on their own experiences, no one would dispute the claim that some pain is more severe than others. At the same time, no one is suggesting that medical professionals ought to address the pain caused by a paper cut with the same urgency that they would treat the pain caused by a broken rib. The crucial point is that the fact that someone may be experiencing "relatively minor" pain should not be used to dismiss that pain as insignificant. The current law's focus on "intractable" pain—i.e., pain that is not easily alleviated—is "symptomatic" of the more general expectation that medical professionals must solve all problems, no matter how difficult. Health care providers and their patients should acknowledge the value of such victories, rather than always expecting medical professionals to be able to cure all problems.

Response:

The references to "intractable" pain were added by legislation that was designed to acknowledge the special needs of people who suffer from chronic pain. Although chronic pain is not necessarily more "worthy" of receiving treatment than less severe forms of pain, it is *chronic* pain that is primarily responsible for pain's impact on individuals' ability to engage in a healthy social and family life and to be productive members of the work force. By eliminating references to "intractable" pain, the bills may divert attention away from chronic pain in the short-term only to force the legislature to revisit the issue in several years.

For:

House Bill 5148 would authorize the application of stickers or decals to a driver's license to indicate that the licensee had designated a patient advocate. It would also the license to authorize the inclusion of a statement that the licensee carried an emergency medical identification card. House Bill 5266 would authorize the application of stickers or decals to a state personal identification card to indicate that the cardholder held an emergency medical information card or had made certain provisions for end of life care. Terminating curative care for a patient is extremely difficult to justify absent a clear indication from a patient (or authorized representative) that the patient supports such action. Despite their sincere wishes to respect patients' preferences, medical personnel—particularly those providing emergency health care services—consistently report difficulty determining whether their patients have exercised certain options that would help clarify what their wishes are, where medical information and other information pertaining to their wishes can be found, and who is authorized to speak on their behalf. An advance directive, designated advocate, or do-not-resuscitate order is only effective if it is readily accessible. A driver's license or a state personal ID card would be a logical place for an individual to be allowed to indicate that he or she held an emergency medical information card or had made certain other provisions for the end of life. Just giving people the option to do so could encourage them to think about such issues. Moreover medical personnel would know that the license or ID card could provide such information and would thus look for such a card when treating an individual who is unconscious or legally incompetent. This would help ensure that a patient's wishes were followed.

Moreover, permanently adding the $1 service fee to the $6 state ID card fee would allow the secretary of state's office to cost-effectively maintain the digital ID card program. Without the additional dollar per card, the office is concerned that it would have to eliminate the use of digital photos and bar codes.

Response:

One unintended consequence of allowing people to indicate on a driver's license or a state ID card that they carried an emergency medical information card or had made certain provisions for end of life care may be that medical personnel who do not look for or find the card, for whatever reason, could be held liable for forgetting or failing to do so. While everyone agrees that it makes sense to make such information as accessible as possible, medical personnel are already under a great deal of pressure in situations where patients are unconscious or legally incompetent, and it would be wrong to contribute to this pressure.

Reply:

Although medical personnel will hopefully look for a patient's state identification card, the bill contains no suggestion that they could be held liable for forgetting or failing to do so.

Against:

The bills ignore some key points of the commission's report and thus do not do enough to ensure that patients will receive adequate and appropriate care. Notably, the bills fail to address the problems with reimbursement that the commission identified as barriers to care. According to the commission's report, approximately 70 percent of people who die in the U.S. in any given year are covered by Medicare, and about 13 percent are covered by Medicaid. Moreover, Medicare's reimbursement policies often serve as a model for other insurers that cover hospice services. Despite the wide range of hospice services covered by these programs, they do not reimburse fully for certain costs associated with hospice care. For instance, Medicaid only pays 95 percent of room and board for nursing home patients receiving hospice care services, and Medicare does not pay room and board for any patients receiving hospice care services. Such "underfunding" is a significant disincentive to nursing homes and hospitals that contract with hospice care providers. The commission also suggested that the Medicare hospice benefit rate may be outdated, given the rise in costs of prescription drugs and "outliers." Hospitals and nursing homes that know they will not receive adequate reimbursement for providing hospice and palliative care services will not provide these services unless they are able to work out alternative arrangements with the service providers to neutralize the difference in cost and reimbursement. While many hospitals and nursing homes are able to do this, problems with reimbursement raise serious barriers to the provision of adequate and appropriate pain and symptom management for patients nearing the end of life.

None of the bills address the fact that providers generally only cover hospice care after a prognosis of six months or less of life remaining has been made. According to the commission, this is "a regulation based on research of the cancer disease trajectory and not including other terminal illnesses." Something needs to be done to ensure that patients who have a reduced life expectancy due to advanced illnesses *other than cancer* are receiving adequate, appropriate care. The commission stated that "many other diseases have different disease trajectories, with longer courses and less predictability. For example, it is difficult to identify which hospitalized patients with advanced congestive heart failure, chronic obstructive pulmonary disease, or end-stage liver disease will probably die within six months. In short, these diseases do not fit the Medicare reimbursement model for hospice care." Further, assuming that six months is an adequate time frame for *patients with cancer*, more needs to be done to ensure that the full amount of permitted time is used. According to a study by the U.S. General Accounting Office that found that from 1992 to 1998 the national average length of stay for hospice patients covered by Medicare declined from 74 to 59 days and the national median length of stay declined from 26 to 19 days. Delays in referrals and treatment become a quality of care issue insofar as they lead to the " . . . use of more crisis services, which are more costly and deprive the patient of the pain and symptom management at which palliative care and hospice programs particularly excel." In sum, 19 days is simply not enough time for patients to reap the full benefits of hospice care.

Response:

Federal law and most insurers define a terminally ill patient to be a patient who has a prognosis of six months or less of life. Regardless of whether the time frame is ultimately based only on the cancer disease trajectory, the bills do make a significant effort to encourage patients and providers to consider the need for hospice care and other end of life care services earlier than they have been doing. This is an important first step.

POSITIONS:

The Department of State supports House Bills 5148 and 5266. (11-16-01)

The Michigan Health and Hospital Association supports the bills. (11-15-01)

The Great Lakes Association of the American Cancer Society supports the bills. (11-16-01)

The Michigan Hospice and Palliative Care Organization supports the bills. (11-16-01)

The Michigan State Medical Society supports the bills. (11-19-01)

The Detroit Field Division of the federal Drug Enforcement Administration would support House Bills 5260-5262 with an amendment to require a secure, "tamper-resistant" prescription form. (11-15-01)

The Michigan Pharmacists Association would support all the bills with an amendment to require a secure, "tamper-resistant" prescription form. (11-19-01)

The Michigan Association of Substance Abuse Coordinating Agencies opposes House Bills 5260-5262. (11-19-01)

Analyst: J. Caver

■This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.