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THE APPARENT PROBLEM:

The official triplicate prescription form program for Schedule 2 prescription drugs was enacted by the legislature (Public Act 60 of 1988, enrolled Senate Bill 75) as part of a larger anti-crime package of legislation. The program was intended to address the problem of the diversion and abuse of Schedule 2 prescription drugs, where prescriptions are diverted from legitimate medical uses to illegal, but highly lucrative, sales on the street. (Of the five classes, or "schedules," of drugs in the Public Health Code, Schedule 2 drugs include controlled substances with legitimate medical use but with a high potential for addiction.) The program required a triplicate prescription form for each prescription for a Schedule 2 drug and created a Controlled Substances Advisory Commission (CSAC), which was to issue annual reports and evaluate the effectiveness of the program.

To pay for the official prescription form program, Public Act 61 of 1988 (enrolled Senate Bill 76) temporarily increased drug license fees by \$20 a year, from a \$30 annual fee to a \$50 annual fee. Public Act 81 of 1993 (enrolled House Bill 4076) permanently increased these temporary annual fees by another \$25, to \$75 a year, until September 30, 1993, at which time they are to drop by \$20 to \$55 a year. (The 1993 fee increase was part of a package of bills that revised the health care professions disciplinary process. Part of that package increased the annual license and registration fees for health professionals in order to pay for this new process.)

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 have virtually eliminated forged prescriptions for these drugs. The commission's evaluation report recommended a number of changes in the program, including dropping Ritalin from the triplicate prescription program, using a state-controlled single-copy

EXTEND OFFICIAL PRESCRIPTION FORM PROGRAM

House Bills 4117 and 4118 as enrolled Second Analysis (3-14-94)

Sponsor: Rep. Sharon Gire House Committee: Public Health

Senate Committee: Health Policy

prescription form issued by a private vendor, and creating an electronic data transfer option for prescribers and pharmacists so that information can be directly transferred via an "on line" computer system or by floppy disk.

Legislation has been introduced to extend both the official prescription form program and the \$20-increase in annual drug license fees past their current September 30, 1993, expiration date, and to implement some of the Controlled Substances Advisory Commission's recommendations.

THE CONTENT OF THE BILLS:

The bills would eliminate the September 30, 1993, expiration date on the official triplicate prescription form program established by Public Act 60 of 1988 and on the \$20 increase in drug license fees established by Public Act 61 of 1988. House Bill 4117 would amend the Public Health Code (MCL 333.7111 et al.) to keep the official prescription form program (including the Controlled Substances Advisory Commission) and House Bill 4118 would amend the State License Fee Act (MCL 338.2251) to keep the annual fee for licenses to manufacture, distribute, dispense, or prescribe controlled substances at \$75, rather than allowing it to decrease by \$20 after September 30, 1993.

The bills also would implement a single sheet official prescription form, establish a standard computer format for transferring prescription-related information, and create three restricted funds: the official prescription form program fund, the health professions regulatory fund, and the nurse professional fund.

More specifically, the bills would do the following:

Single sheet official prescription forms. Currently, official prescription forms for Schedule 2 drugs are

serially numbered and in triplicate. The prescriber keeps copy 3 of the form, signs copies 1 and 2, and gives these copies to the patient ("the person authorized to receive the prescription"). The patient takes copies 1 and 2 to a pharmacist, who forwards copy 1 to the department and keeps copy 2 for his or her records.

The bill would, beginning January 1, 1995, substitute a single sheet official prescription form for the current triplicate form, and would suspend the provisions concerning the new single sheet form until the department implemented the program to transmit required information electronically (or on storage media). Prescribing practitioners (such as physicians) would give the single sheet form to the patient, and would 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 (or, in the case of veterinarians, in the record of the owner of the animal for whom the prescription was prescribed). When a pharmacist received a single sheet official prescription form from a patient, he or she would then forward the form to the department or transmit the information electronically or on storage media. pharmacist sent the official form to the department, he or she would be required to keep a copy of the form.

Standard computer format. Currently, the health code also requires the Controlled Substances Advisory Commission (in conjunction with the DLR and the Michigan Pharmacists Association) to establish, by August 1, 1990, a standardized computer data base format that could be used by pharmacies dispensing Schedule 2 drugs to transmit the required prescription-related language electronically or on storage media. Within two years after that, the commission is to evaluate whether or not there is a continued need for triplicate prescription forms and to report to the legislature. Finally, currently, if a prescribing practitioner fails to completely fill in all of the required information on the front of an official prescription form, the act allows pharmacists to fill in the missing information on the back of the form.

House Bill 4117 would amend the Public Health Code to:

* set a December 31, 1993 date for the Department of Commerce (rather than the Controlled Substances Advisory Commission) to

establish a standardized computer format (consistent with the standards of the National Council for Prescription Drug Programs) for the electronic transfer to the department of the information required on the first copy ("copy 1") of the triplicate prescription form.

- * require the commission to approve or revise the format within three months after the department established the format;
- * require the department, upon commission approval or revision, to implement transmission of information under the format;
- * allow both practitioners and pharmacies to transmit the required prescription-related information to the department electronically or on storage media after the commission approved or revised the format;
- * allow pharmacists to forward the first copy of an incompletely filled-out prescription form to the department and to inform the department that the dispensing practitioner had not completely filled out the form as required; and
- * drop the requirement that the Controlled Substances Advisory Commission evaluate the continued need for triplicate prescription forms and report to the legislature within two years after establishing electronic or storage media transmission of required data.

Official prescription form program fund. addition to repealing the September 30, 1993, sunset on the temporary \$20 drug license fee increase, House Bill 4118 also would amend the Public Health Code to establish an "official prescription form program fund" in the state treasury that would be administered by the Department of Commerce, and that would require that \$20 of each controlled substances license fee be deposited into the fund. (This would constitute an exception to the requirement that fees collected under the license fee act be credited to the state general fund.) The department could use the fund only for programs relating to the official prescription forms required for Schedule 2 drugs. Any unspent balance in the fund at the end of the fiscal year would be carried forward to the next fiscal year and wouldn't lapse into the state general fund.

The nurse professional fund. House Bill 4117 would repeal, and reinstate, a section (16315) of Public Act 87 of 1993 (enrolled Senate Bill 343), which is part of the health care disciplinary reform package of legislation passed earlier this session. The bill, basically, would transfer from Public Act 87 the creation of a nurse professional fund to promote and advance the nursing profession. Two dollars of every annual nursing license fee would go to the fund, which also could receive gifts and other money as allowed by law. The bill would say that the Department of Commerce could use not more than one-third of the fund each year for the following: (1) one-third to establish and operate a nurse continuing education program, (2) one-third for research and development studies to promote and advance the nursing profession, and (3) onethird to establish and operate a nursing scholarship program. Within two years after the bill took effect, the department would be required to promulgate rules regarding expenditure of money from the fund, including rules governing the continuing education program and rules establishing eligibility criteria for participation in the scholarship program.

Health professionals regulatory fund. House Bill 4117 also would, in repealing and reinstating Section 16315, create a health professions regulatory fund in the treasury, to which health professionals' licensing fees would be credited (except for the money from nurses' license fees that would go to the nurse professional fund). The state treasurer would direct the investment of the fund, and interest and earnings from the investment also would be credited to the fund. The unencumbered balance in the fund at the end of the fiscal year would stay in the fund (and not revert to the state general fund). The Department of Commerce would use the fund only to carry out its powers and duties under the health code.

Fees. Under the triplicate prescription legislation (Public Act 61 of 1988), the \$30 annual drug license fee was raised by \$20 to \$50 until September 30, 1993. Meanwhile, Public Act 80 of 1993 increased the annual license fee by \$25 to \$75, but kept the September 30, 1993, date for decreasing the annual fee by \$20 (to \$55).

House Bill 4117 would repeal the section of Public Act 80 of 1993 that sets drug license fees, and would instead amend the Public Health Code to require a \$10 application fee and a \$75 annual license fee. (That is, it would not decrease the

annual license fee by \$20 on September 30, 1993.)

Department of Commerce. The Public Health Code currently requires dispensing pharmacists and practitioners to forward to the Department of Licensing and Regulation (DLR) the first copy of the official triplicate prescription form (which is used to prescribe Schedule 2 drugs) by the 15th of the month in which the prescription is completed. House Bill 4117 would delete references to the Department of Licensing and Regulation, substituting instead references to the Department of Commerce, to which the former department's duties were transferred.

Required reports. House Bill 4117 would require the Department of Commerce, by September 30, 1997, to submit a public report to the governor, the legislature, and, upon request, statewide health professions organizations whose members held drug licenses. The department also would be required to make the report available to other people who were interested in it. The report would evaluate the effectiveness of the official prescription form program in reducing the diversion of Schedule 2 drugs; any related increase in the use of Schedule 3, 4, or 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, as well as any changes the department recommended be made in the program.

Other provisions. House Bill 4117 would allow Schedule 2 prescriptions for terminally ill patients to be partially filled in increments for up to 60 days after the date the prescription was issued. The bill also would require that a prescription for an androgenic anabolic steroid be filled within five days after it was issued, rather than three. Finally, the bill would exempt methylphenidate (Ritalin) from the official prescription form program.

Repealers, effective date. Currently, health care professions' license fees (including a drug license fee) are set by the State License Fee Act (Public Act 152 of 1979). The legislative package revising the health care disciplinary process, which passed earlier this session, moved health professional's license fees back into the Public Health Code. Although House Bills 4117 and 4118 originally were not part of the health care disciplinary package, House Bill 4117 would repeal two sections of two acts in that package, while another of the acts in the package would repeal most of House Bill 4118.

House Bill 4117 would repeal -- and partially reinstate -- two sections of the Public Health Code added by two public acts that are part of the health care disciplinary package of legislation passed earlier this session. Section 16315 of Public Act 87 of 1993 (enrolled Senate Bill 343) establishes the health professions regulatory fund and the nurse professional fund; section 16319 of Public Act 80 of 1993 (enrolled House Bill 4076), increases annual drug license fees by \$25 (from \$50 a year to \$75 a year) but keeps the September 30, 1993, repeal of the \$20 fee increase for the triplicate prescription form program (so the annual license fee would drop to \$55).

House Bill 4117 would reinstate these two sections (16315 and 16319), but without the sunset on the \$20 triplicate prescription surcharge on drug licenses. House Bill 4117 also would take effect immediately, except for the two sections (16315 and 16319) that add the drug license fees and create the three funds (the health professions regulatory fund, the nurse professional fund, and the official prescription form program fund). These sections wouldn't take effect until section 16317 of Public Act 80 of 1993 (enrolled House Bill 4076), which allows the Department of Commerce to increase drug and health professions license fees, takes effect (which is 90 days after the legislature adjourns at the end of the year).

Finally, until Public Act 87 of 1993 (enrolled Senate Bill 343) took effect, House Bill 4118 would amend section 51 of the State License Fee Act (Public Act 152 of 1979) to establish an official prescription form program fund and to set annual drug license fees at \$50. Public Act 87 of 1993 (enrolled Senate Bill 343), which takes effect 90 days after the legislature adjourns at the end of the year, repeals this section of the State License Fee Act.

<u>Tie-bar</u>. House Bills 4117 and 4118 are tie-barred to each other.

BACKGROUND INFORMATION:

Drug license fee legislation. Drug license fees were changed by two successive pieces of legislation in 1988: Public Act 61 of 1988 (enrolled Senate Bill 76) temporarily raised the fees to \$50, placing a \$20 triplicate prescription program surcharge on the \$30 annual fees until September 30, 1993; Public Act 461 of 1988 (enrolled House Bill 4820) added a \$10 application processing fee, dropped the \$20 late

license renewal fee, and changed the language referring to "controlled substance license" and "controlled substance license renewal" to "license fee, per year, for a pharmacist, pharmacy, manufacturer, or wholesaler, or for research and instructional activities."

Public Act 81 of 1993 (enrolled Senate Bill 343) increased the annual license fee by another \$25 to \$75; after September 30, 1993, when the \$20 triplicate prescription surcharge was to expire, the annual drug license fee was to be \$55. Public Act 79 of 1993 (enrolled House Bill 4295) moved the drug license fees (as well as the health professional license and registration fees) from the State License Fee Act back to the Public Health Code, while Public Act 87 (enrolled Senate Bill 343) repealed the sections of the State License Fee Act that set health professional and drug license fees.

Controlled substances licensees. Controlled substances licenses are issued to pharmacies, pharmacists, certain laboratories, manufacturerwholesalers, and to members of the five prescribing professions: MDs, DOs, dentists, veterinarians, and podiatrists. As of February 1994, the state had issued a total of 46,640 controlled substances licenses. Almost half of these (22,360) went to MDs. The next largest group was pharmacists (8,031), then dentists (5,919), DOs (4,536), pharmacies (2,217), veterinarians (1,662), and podiatrists (611). In addition, there are a small number of "second location" licenses (809), issued to prescribing practitioners with more than one place where they practice, and so-called "special controlled substances licenses" (255) issued to analytical or research laboratories, to physicians who prescribe methadone in methadone programs, and to dog pounds and humane societies for administering sodium pentobarbital.

FISCAL IMPLICATIONS:

According to the April 1993 evaluation report issued by the Department of Commerce (which houses the Controlled Substances Advisory Commission), during the first three years of the triplicate prescription program, the program cost about \$3 million and the \$20 drug license surcharge raised about \$2.7 million in revenues. The Office of Health Services in the department's Bureau of Occupational and Professional Regulation (which replaced the now-defunct Department of Licensing and Regulation) estimated that it would cost

approximately \$800,000 a year to continue the program. (April 1993)

ARGUMENTS:

For:

By all accounts -- including, for example, those of the federal Drug Enforcement Administration (DEA), the Michigan Department of State Police, the Michigan Board of Pharmacy, and the Macomb County Pharmacists -- the triplicate prescription program established by Public Act 60 has virtually eliminated the illegal diversion of Schedule 2 drugs in Michigan.

Two recent federal studies, which in part examined Michigan's program and whose results echoed those of a July 1991 Michigan survey, reported a number of benefits from multiple copy prescription programs. Such programs improve investigators' productivity by helping officials better target their investigations. (For example, the Michigan state police report that information from the triplicate prescription database not only helps them target the worst offenders, but also helps in locating violating pharmacists and pharmacies, as well as identifying patients who go from doctor to doctor to obtain These programs also result in more drugs.) successful prosecutions of drug diversion offenders, reduce the vulnerability of prescriptions to theft and forgery, and appear to have some effect on the abuse of scheduled drugs as measured by hospital emergency room cases of drug abuse. example, in 1988, meperidine [trade name Demerol] was ranked 69th among the top 100 drugs reported in the Detroit area emergency room cases, but by 1990 meperidine had dropped completely off the top 100 list.) The federal studies also reported that physician fears that these programs would adversely affect their ability to practice medicine or would compromise patient care or patient confidentiality have not been substantiated.

The Department of State Police also reports some benefits of the triplicate prescription program in addition to the control of Schedule 2 drugs. Hospitals reportedly have become more aware of the need for tighter controls on these drugs, and hospital administrators reportedly are requesting state police assistance more quickly when drugs cannot be accounted for. Proper documentation of these drugs reportedly is watched more closely, and nurses now have to sign for these drugs. Nursing home operators reportedly are requesting training

programs to enable them to more quickly detect drug diversion, while pharmacists reportedly call the state police more readily when they detect unusual prescribing habits. Finally, many of these agencies reportedly have gone on to voluntarily implement tighter controls for Schedule 3 and Schedule 4 drugs (neither of which fall under the present program).

With regard to health care cost containment, the program also reportedly is saving money. Early studies by Medicaid and Blue Cross indicated that Medicaid was saving \$440,000 a year on narcotic pain relievers alone, while Blue Cross experienced a 30 percent decrease in costs for Schedule 2 drugs without a significant increase in Schedule 3 and Schedule 4 drugs.

In addition, the program appears to have benefitted - and not harmed, as some feared - pharmacy businesses. A representative of one large pharmacy chain in Michigan testified that the chain had not experienced any significant increases in costs of doing business as a result of the program, nor did pharmacists find burdensome the process of mailing the state's copy of the form into the program. The chain's pharmacists also reported feeling safer and more confident about filling Schedule prescriptions since the program's inception: not only are they more confident that the prescriptions are legitimate, but they feel safer about filling them, since due to the program some of the narcotics rings that used to try to get bogus prescriptions filled are now out of business. The pharmacy chain also believes that the triplicate prescription program has made it easier -- rather than, as feared by some, more difficult -- for people with legitimate Schedule 2 prescriptions to get them filled.

An added benefit of the program, moreover, it that it increases prescriber accountability and decreases health care fraud without requiring any taxpayer funding. The program is entirely funded by a \$20 fee that was added to the controlled substances license fees paid by the state's 45,000 licensees.

Under the current triplicate prescription program for Schedule 2 drugs, Michigan has gone from being one of the most (if not the most) significant sources of prescription drug abuse in the nation to being a model and example to other states on how to control this problem. Without these two bills, the program will not continue and the many gains made in controlling the diversion and abuse of Schedule 2 drugs could quickly be lost.

For:

Establishing a restricted fund specifically designated for the implementation of the official prescription form program would ensure that the program would be able to continue to effectively monitor the use and abuse or diversion of prescription drugs. Having dedicated money is essential if the program is to continue, for without such a restricted fund, money collected under the \$20 license surcharge simply goes into the state general fund, without any guarantee that it will be used for the triplicate prescription program. And since the program was established in 1988, money sometimes apparently has been a problem. For example, although the \$20 annual increase in drug licenses raises approximately \$900,000 a year, the Controlled Substances Advisory Commission reported that it held an "abbreviated" meeting schedule in 1991 due to budgetary constraints. (The commission met only once in 1992, and then didn't achieve a quorum). In addition, according to the Controlled Substances Advisory Commission's second annual report (1992), early in 1991 the Michigan Department of State Police had to eliminate almost all of their diversion enforcement efforts because of Although the state police budgetary reasons. received a federal grant later in 1991 and developed a new drug diversion enforcement program, the state police reported that even with the federal grant their resources still were inadequate to allow the same level of investigation as in the past.

Response:

A dedicated fund wouldn't help with cuts in the state police budget, but from the commission's reports it appears that not much investigation into diversion of Schedule 2 drugs is needed anymore. According the to second annual report of the Controlled Substances Advisory Commission (January 1992), the federal Drug Enforcement Administration (DEA) "indicated Schedule 2 drug diversion activity has decreased so substantially since implementation of the Triplicate Prescription Program that it has been able to shift its limited investigative resources to diversion in lower schedules."

For:

Since reportedly 98 percent of pharmacies in the state are computerized, establishing and using computerized data transfer would increase pharmacies' efficiency (and thereby save them money) and decrease state costs by eliminating needless duplication and the labor-intensive nature

of paper systems (which must eventually be transferred to computer anyway).

Response:

The bill would require the Department of Commerce to establish a standardized data base format that could be used to transmit required information of Schedule 2 prescription drugs. Yet, the Department of Licensing and Regulation (now the Department of Commerce) did create a data base format in July 1990 and included it as an appendix in the Controlled Substances Advisory Commission's 1991 annual report.

What is more, it seems unlikely that implementing an electronic data transmission for Schedule 2 drugs would be cost-effective because only a handful of the state's pharmacies (at the time of the 1991 annual report, for example, only 15 of the state's 2,187 licensed pharmacies) submit more than 100 triplicate prescription forms per month to the department. And, since the implementation of the triplicate prescription form program, the number of Schedule 2 drug prescriptions for the most prescribed Schedule 2 drugs other than Ritalin have decreased. In fact, in its 1991 annual report the commission estimated that it would cost \$38,000 to implement the electronic (or storage media) process, not including the costs for on-site auditing of data submitted electronically or on storage media.

Reply:

House Bill 4117 would merely allow an additional form of reporting. It would not mandate reporting by electronic data transfer, nor eliminate the existing paper system. What is more, the bill would require the department to develop a standardized data base format that specifically was consistent with the standards of the National Council for Prescription Drug Programs. Finally, if other drug schedules were to be added to the official prescription form program, electronic data transmission likely would benefit all pharmacies with computer capabilities, not just those with larger volumes of Schedule 2 prescriptions.

Against:

House Bill 4117 doesn't go far enough. Instead of just extending the existing program for Schedule 2 drugs, the bill should expand the program to include the other scheduled prescription drugs (that is, Schedules 3 through 5). According to the federal Drug Enforcement Administration, for example, Schedule 3 codeine products, which are not covered by the existing triplicate prescription program,

currently are a major diversion concern in Michigan. In 1991, Michigan ranked third highest in the nation in per capita distribution of Schedule 3 codeine products, with the largest questionable 1991 purchase of these products in Michigan being 170,000 dosage units! To comprehensively deal with the diversion of prescriptions drugs, all prescription drugs should be covered by the triplicate prescription program.

Against:

The charge to the Controlled Substances Advisory Commission may be too restricted, in the sense that there may be problems with Schedule 2 prescription drugs other than that of diversion for sale on the street. Specifically, the distribution and use in Michigan of Ritalin (the brand name for the Schedule 2 drug methylphenidate), which most often is used to treat attention deficit hyperactivity disorder (ADHD), is extremely high. Michigan ranks first in the nation for the prescription and distribution of Ritalin. In fact, the distribution of Ritalin in Michigan has been as much as 205.4 percent of the national average. The commission found little diversion or abuse of Ritalin, but both before and since the triplicate prescription program, Ritalin has been almost 50 percent of the Schedule 2 controlled substances prescribed in Michigan. In fact, Ritalin prescriptions (and the total doses prescribed) have increased since implementation of the program.

The commission noted that the high interest in ADHD at some Michigan universities might explain a Ritalin use rate higher than in other states, but the commission wasn't convinced that this was sufficient reason for Ritalin consumption in Michigan to be over 200 percent of the national average. Michigan's rate of use of Ritalin, even in the absence of diversion, should be examined further.

Against:

The program, while perhaps decreasing illegal diversion of Schedule 2 prescription drugs, also could have a chilling effect on the prescription of painkillers by physicians, thereby worsening an existing problem that many patients -- some of whom are terminally ill -- have in getting adequate pain relief for their illnesses or injuries.

In fact, some people claim that the current push to legalize "assisted suicide" is a direct result of health professionals' reluctance to provide these patients with adequate pain relief. It reportedly is not true that much of the seemingly intractable pain experienced by many patients cannot be alleviated with currently existing drugs; the problem seems to be that physicians are trained to avoid the use of effective pain killers for fear of being prosecuted for "over prescribing" these drugs. As a result of this systematic under-prescribing of effective pain killers, however, some people then believe that their only alternative to living with unbearable pain is to end their lives. The official prescription form program, while well-intended, also has the undesirable side-effect of reinforcing physicians' fears about prescribing pain medications.

It is worth noting, moreover, that approximately 57 percent of respondents to a November 1990 Department of Licensing and Regulation (DLR) survey agreed or strongly agreed that prescribers could benefit from more education on pain management and the use of Schedule 2 controlled substances in pain management. And a recent article in the New England Journal of Medicine reports that 40 percent of cancer patients are undertreated for pain. So it seems clear that inadequate pain management is a problem that needs to be addressed and that certainly should not be exacerbated.

Response:

According to the DLR's survey of prescriber perceptions of the triplicate prescription program, approximately 80 percent of the respondents (based on 1,244 responses from members of the five prescribing professions: MDs, DOs, dentists, podiatrists, and veterinarians), indicated that the triplicate prescription program didn't prevent them from providing the needed Schedule 2 medication to Although nearly 11 percent of the patients. respondents either disagreed or strongly disagreed with the statement that the program did not have a "chilling" effect on their prescribing practices, it is possible that this disagreement resulted from prescriber misunderstanding of the program requirements. For example, a few prescribers apparently wrote to the program to complain that filling out the triplicate prescription form took much longer than the standard prescription form, even though the only information required on the triplicate prescription form that isn't required on the standard form used for all non-Schedule 2 drugs is the patient's age. Some prescribers complained about the requirement to fill in the patient's name, address, and age, but the patient's name and

address have been required on prescriptions by both state and federal law for many years before the triplicate prescription program was enacted. Finally, some prescribers complained of a requirement that prescriptions be rewritten monthly or that patients be reexamined monthly. Yet these aren't requirements of the triplicate prescription program, but rather may be requirements of insurance programs. For example, some insurance providers limit payment for the quantity of any Schedule 2 prescription to a 30-day supply, while some policies require physician-patient contact at each 30-day interval. Although these policies are unrelated to the triplicate prescription program requirements, they sometimes are (mistakenly) attributed to the triplicate prescription program law.