F I S C A L I M P A C T R E P O R T

SPONSOR Papen **ORIGINAL DATE** 02/04/13 **LAST UPDATED** 02/20/13 **HB**

SHORT TITLE Prescription Drug Insurance Coverage Review **SB** 296/aSCORC/aSPAC

ANALYST Geisler

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY13	FY14	FY15	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total		NFI, See Amendment				

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION
LFC Files

Responses Received From
Human Services Department (HSD)
Public School Insurance Authority (PSIA)
General Services Department (GSD)
Public Regulation Commission (PRC)

SUMMARY

Synopsis of SPAC Amendment

The Senate Public Affairs Committee amendment to Senate Bill 296 changes the period of time for insurance companies, health maintenance organizations, health care plans and Medicaid contractors, etc. to approve prior authorization requests for prescriptions from two to three business days upon receipt of the request.

Synopsis of SCORC Amendment

The Senate Corporations and Transportation Committee amendments to Senate Bill 296 address concerns about implementation of an electronic prior approval process for prescriptions by delaying implementation for 2 years after the adoption of national standards. The bill as amended now reads that "No later than twenty-four months after the adoption of national standards for electronic prior authorization, a health insurer shall exchange prior authorization requests with providers who have e-prescribing capability." The bill still requires development of a uniform prior authorization form, and requires a decision on the prescription request within 2 days or shall be considered approved.

As amended by SCORC, there is no fiscal impact identified due to the delay in implementing the electronic approval process.

Synopsis of Original Bill

Senate Bill 296 (SB 296) requires that effective January 1, 2014, Medicaid contractors, insurers and HMO's will accept use of a uniform prior authorization (PA) form for prescription drugs from prescribing practitioners in the state. Development of the standards will take place with input from stakeholders, including the Board of Pharmacy. At a minimum, the prior authorization must be made available electronically and may not exceed two pages. The PA forms may be electronically submitted to the health insurer, and PA's not acted upon within two days will be deemed approved.

FISCAL IMPLICATIONS

Although not quantified, moving to electronic prior-authorizations is expected to improve efficiency of the state health insurance plans for employees, teachers and retirees who currently respond to inquiries almost daily on the need for, or status of, prescription prior authorizations.

SIGNIFICANT ISSUES

The Public Regulation Commission (PRC) notes that a universally usable prescription authorization form as contemplated in this bill would likely be beneficial for practitioners, consumers and other parties. In particular, consumers would benefit from the elimination of inherent delays in approval of the PA form which prevents dispensing of needed medication.

The Public School Insurance Authority (PSIA) notes that this bill will solve problems in the timely delivery of prescriptions noted in a 2010 Minnesota report: "While prescription drugs requiring prior authorization (PA) make up only a small fraction of all medications, studies have also reported that "PA is a widely adopted method of drug utilization management" and prior authorizations are "frequently used to manage the increasing costs of pharmacy benefits." One large online survey found that nearly two-thirds of prescribers write prescriptions that require PA. Over time, prescription drug prior authorizations have become an increasingly more frequent transaction. One study reported that "advances in MTM [medication therapy management], biotechnology, designer drugs, specialty pharmacy, and the cost of the pharmacy benefit, has increased the number of medications requiring a PA." As a result, "from 2000 to 2006, commercial plans doubled the number of medications requiring PA," and the number "increased steadily" among Medicaid programs"

The Human Services Department (HSD) notes the Medical Assistance Division would be required to develop the ability to receive and reply in an electronic transaction format that is not a national standard transaction, even though it is unknown if any providers could really use it. Provider acceptance of some electronic transactions, such as e-prescribing, has been a national problem. The bill does not take into account the difficulty of this task. See additional discussion under "Administrative Implications" and "Other Substantive Issues."

The HSD provided concerns on two-day approval process:

The provision that requires the request to be deemed approved if the healthcare payer does not respond in 2 days is problematic. Often, in order to approve use of a drug, the approving agency

may need to know if alternatives have been considered or tried ("step therapy"), if there is a documented or suspected allergy to a preferred drug; and perhaps lab data or other medical notes to document the need for an item. SB 296 does not address potential issues involved with the provider not including all the essential information the MCO needs to make a decision regarding medical necessity. Also, many physicians' offices close on Friday resulting in a 3 day period during which the prescriber may not be able to be contacted by the authorizing entity. When Monday is also a holiday, the provider may be out of contact for 4 days.

In requiring a default decision after 2 days that the drug is considered approved, makes the incorrect assumption that approval of the drug is in the patient's best medical interest, which is not necessarily the case. Preferred drug lists are usually constructed with a view to medical criteria, safety, and side effects, in addition to cost. Under the provisions of SB 296, a drug with known side effects could be defaulted to "approved" based on time, when a less dangerous drug could be medically preferred. Also, authorizations are also going to be used in the near future to approve longer term use of narcotic drug items, higher than normal doses of drugs that are subject to abuse, and other purposes that relate to inappropriate over utilization of drug items.
Many payers have a standard that the denial of a request can only be done after a physician review, while approval of a request can be done by a lower level health professional working from standard criteria. The 2 day turn-around required may not allow for the higher level review when the physician reviewer must become involved to assure the best decision is made in approval or denial of a request.

ADMINISTRATIVE IMPLICATIONS

The HSD notes that the bill requires the electronic data interchange standards to be developed by the board of pharmacy in consultation with the insurance division of the PRC. Developing electronic transmission standards that will integrate into providers' existing practice management systems and other HIPAA compliant electronic software is technically very challenging.

The existing, currently available, "NCPDP Telecommunication Standard" for electronic prior authorizations was developed by highly qualified individuals working for very experienced standards development organizations, but proved to be too cumbersome for most providers to use and, therefore, was not adopted as a national standard for HIPAA. Currently the NCPDP has been authorized by national standards authorities to test a new electronic transaction for electronic prior authorizations for HIPAA adoption. That process is currently underway. It is unlikely that the electronic transaction described in the bill could be developed to the necessary technical standards including HIPAA privacy and security provisions without hiring experienced technical consultants, though the bill provides no money for consultant contracts.

TECHNICAL ISSUES

It is not clear if submission of PA's "electronically" includes via a fax, or whether the intent of the bill is for submission via other electronic means.

OTHER SUBSTANTIVE ISSUES

<u>The HSD provided concerns on implementation of uniform PA form</u>:

There is nothing in the bill that specifies that any submission on the part of the provider must be on secure networks that meet the HIPAA privacy and security standards. Typically, that could

only be assured if the healthcare payer (in this case the Medicaid managed care organizations and the Medicaid Fee-for-Service fiscal agent) sets up a specific web portal site for the information to be submitted. The prescriber would then have to either upload the information or complete an on-line version of the form. Standards for an electronic signature would have to be developed. Simple e-mail would not meet the mandatory HIPAA standards to submission of the form.

The same issue applies regarding a response to a provider. Again, simple e-mail could not be used because of HIPAA security standards regarding protected health information (PHI). There is nothing that assures the provider receiving the authorization response is using a secure network. The only way security could be assured is for the prescriber to return to a web portal site to review a response unless other encryption standards were established as part of the process. Given the complexity of the transactions that must be developed in order to meet the HIPAA privacy and security standards for accepting and responding to the authorization request, it is not reasonable to require the provision to be in place by January 1, 2014. It is likely that payers would need approximately 24 months' notice to implement these provisions that are in addition and distinct from the national standards.

It is very costly for payers to implement an electronic transaction that is not supported at the national level. Any transaction standards developed at the state level will ultimately be short-lived and difficult for payers and providers. The providers' own software is typically developed following federal standards rather than state-specific, standards. An electronic transaction that serves the same purpose has been authorized by the American National Standards Institute (ANSI) and is currently in the testing phase as a national electronic transaction, with the intent that this national transaction will become the HIPAA standard.

ALTERNATIVES

The HSD notes that virtually all of the issues described above could be avoided if the bill called for developing a standard paper form that could be faxed to the healthcare payer. Many physicians fax prescriptions so it would work well in their office model. Pharmacies currently receive faxes. Fax technology meets HIPAA standards for communication and is still an efficient technology when factors like lab data, accompanying medical record pages, and physician signatures are required. This would be a more reasonable solution until the national standard electronic transaction is available.

However, the PSIA suggests that faxes may not be a solution, noting that current PA's are faxed and the PSIA is aware of difficulties with faxes being received or located by its PBM. It may be useful to consider eliminating a fax as an electronic means as defined in the bill.

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

Physician offices will continue to have to identify and use the appropriate PA form for the specific member's PBM. Delays in filling prescriptions will continue.

The HSD notes that the payers and the prescribers would all follow the federal HIPAA transaction standards when the prior authorization form is tested nationally and implemented. Currently, the Medical Assistance Division of the HSD has already established plans to meet with the Medicaid managed care organizations to being to standardize some procedures among

each of the plans and the prior authorization process is one of those items scheduled for discussion.

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