

**Minnesota Department of Human Services  
Licensing Division**

**STATEMENT OF NEED AND REASONABLENESS**

**Proposed Amendment to Licensing Rules Regarding Syrup of Ipecac Requirement, Minnesota Rules, parts 9502.0435, subpart 7; 9503.0090, subpart 1; 9503.0125; 9503.0140, subpart 16; and 9555.9720, subpart 1.**

**Governor's Tracking No. AR235**

**INTRODUCTION**

The Department of Human Services has the authority to adopt rules governing the licensing of child care and adult day services providers. Current rules require licensed child care and adult day services providers to keep syrup of ipecac in their first aid kits and, for children in care, to obtain permission from parents to administer syrup of ipecac. Medical authorities, however, now recommend that syrup of ipecac no longer be used routinely as a poison treatment strategy; that caregivers dispose of existing supplies of syrup of ipecac immediately or, at the very latest, when the expiration date is reached; and that caregivers refrain from buying new supplies of syrup of ipecac. To bring the rules governing licensed child care and adult day services providers into compliance with current medical recommendations regarding the use of syrup of ipecac, the Department is proposing to repeal the provisions in the licensing rules that require these licensed providers to keep and to obtain permission to administer syrup of ipecac. The Department of Pediatrics at the University of Minnesota provided consultation and advice on the rule changes and supports the proposed changes.

**ALTERNATIVE FORMAT**

Upon request, this Statement of Need and Reasonableness can be made available in an alternative format, such as large print, Braille, or cassette tape. To make a request, contact Jodi Pope at the Department of Human Services; 444 Lafayette Road North; St. Paul, Minnesota 55155-3816, (651) 284-4204; (651) 284-4204; Fax: (651) 297-3173; [jodi.pope@state.mn.us](mailto:jodi.pope@state.mn.us). TDD users can call the Minnesota Relay Service at 711 or (800) 627-3529. For the Speech to Speech Relay, call (877) 627-3848.

**STATUTORY AUTHORITY**

The Department's statutory authority to adopt the rules is set forth in Minnesota Statutes section 245A.09, subdivision 1, which provides that "[t]he commissioner shall adopt rules under chapter 14 to govern the operation, maintenance, and licensure of programs subject to licensure under this chapter." Under this statute, the Department has the necessary statutory authority to adopt the proposed rules.

Minnesota Statutes, section 14.125, does not apply here because Minnesota Statutes, section 245A.09, subdivision 1, was adopted and effective before January 1, 1996 and because this rulemaking is an amendment of rules.

## **REGULATORY ANALYSIS**

Minnesota Statutes, section 14.131, sets out seven factors for a regulatory analysis that must be included in the SONAR. The paragraphs below quote these factors and then give the agency's response.

### **Factors (1), (2), (5) and (6):**

**(1) “a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule;” (2) “the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues;” (5) “the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals;” and (6) “the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals.”**

Licensed child care and adult day services providers will benefit from the proposed rules because they no longer will need to buy syrup of ipecac to have on hand and, in the case of child care providers, will no longer need to obtain permission from parents to administer syrup of ipecac. Licensed providers also will benefit from the proposed rules because they will be able to comply more easily with current medical recommendations regarding the use and retention of syrup of ipecac. Providers currently can follow the new syrup of ipecac recommendations only by obtaining a variance from the syrup of ipecac provisions in the licensing rules. Although licensing authorities routinely grant these variances, providers still must spend the time and effort necessary to apply for and obtain the variances. If the proposed rules are adopted, licensed providers no longer would need to get licensing variances before following the new syrup of ipecac recommendations. Also, some providers have reported to the Department that they are having difficulty finding and buying syrup of ipecac because many local pharmacies have discontinued selling this remedy. If the proposed rules are adopted, licensed providers would benefit because they no longer would need to spend the time necessary to find a pharmacy that continues to sell syrup of ipecac. The Department cannot identify any probable costs, either monetary or otherwise, that providers will bear to comply with the proposed rules. If the proposed rules are not adopted, however, providers who want to comply with the new syrup of ipecac recommendations would continue to bear the cost of obtaining variances to do so.

Children and adults using the services of licensed child care and adult day services providers will benefit from the proposed rules because ensuring that licensed providers can easily comply with the most current medical recommendations protects the health and safety of those in their care. The Department cannot identify any probable costs, either monetary or otherwise, that

children and adults using the services of licensed providers will bear to comply with the proposed rules. If the rules are not adopted, however, these children and adults would bear any consequences that might arise when their caregivers cannot easily follow the most recent medical recommendations regarding the use of syrup of ipecac.

The Department's Licensing Division and county licensing agencies will benefit from the proposed rules because these entities will not have to spend the time and money necessary to process variance requests from providers who want to comply with the new syrup of ipecac recommendations. The Department of Human Services has licensing authority over child care and adult day services centers. The Department has delegated its licensing authority over family child care and family adult day services providers to county licensing agencies. As discussed above, a licensed provider who wants to comply with the new syrup of ipecac recommendations must seek a variance from the current licensing rules. The appropriate licensing authority then must spend time and money to process that request. Amending the rules as proposed will remove the need for providers to request syrup of ipecac variances, thereby saving licensing authorities the time and money necessary to process those requests. If the rules are not amended as proposed, licensing authorities will continue to bear the costs of processing variance requests.

The proposed amendments will not cause any additional implementation costs for the Department or county licensing agencies because the Department plans to notify county licensing agencies and license holders about the repealed requirements through regular communications it already has with these entities.

The proposed amendments will not cause any additional enforcement costs for the Department or county licensing agencies because these amendments remove a requirement from the licensing rules. Consequently, during inspections, the licensing authority will not need to verify that the license holder has syrup of ipecac and any required permission forms on hand. Because the proposed rules eliminate only one item from the license holder's first aid kit and only one parental authorization form, however, the proposed rules probably will not significantly reduce the time necessary for inspections and will not generate any significant cost savings or revenue to the Department or county licensing agencies.

The Department cannot identify any additional probable costs, either monetary or otherwise, that the Department or county licensing agencies will bear to comply with the proposed rules.

The proposed rules will not generate any probable costs or revenue to any other state agency because no other state agency is involved in the licensing process for child care and adult day services providers.

**Factors (3) and (4):**

**(3) "a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule" and (4) "a description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule"**

The purpose of the proposed rules is to ensure that licensed providers can protect the health and safety of those in their care by following current medical recommendations about the use and retention of syrup of ipecac. Specifically, medical authorities no longer recommend that caregivers keep syrup of ipecac on hand or use it as a poison treatment strategy. Providers, however, currently must keep syrup of ipecac on hand and must obtain permission from parents to administer it because the licensing rules require them to do so. The Department could continue granting variances from the syrup of ipecac licensing rules to providers upon request but this practice is costly and time consuming for providers and licensing authorities. Repealing the syrup of ipecac licensing rules is a more direct way of ensuring that providers can comply with the new syrup of ipecac recommendations. As discussed above, repealing the syrup of ipecac rules will not be costly or intrusive for providers, the children or adults in care, or licensing agencies. In short, because it is the syrup of ipecac licensing rules that prevent providers from easily complying with current syrup of ipecac recommendations, repealing those rules is the least costly, least intrusive, and most direct way of ensuring that providers can follow the new syrup of ipecac recommendations.

Because repealing the syrup of ipecac licensing rules is the least costly, least intrusive, and most direct way of removing the barrier that keeps providers from following recent medical recommendations regarding the use of this medication, the Department did not seriously consider any other alternatives to this approach.

**Factor (7):**

**(7) “an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference”**

There are no federal regulations setting licensing requirements for child care or adult day services providers. Consequently, there are no differences between the proposed rules and existing federal regulations.

**PERFORMANCE-BASED RULES**

Minnesota Statutes, sections 14.002 and 14.131, require that the SONAR describe how the agency, in developing the rules, considered and implemented performance-based standards that emphasize superior achievement in meeting the agency’s regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals. The agency’s goal here is to protect the health and safety of children and adults receiving day care services. To meet that goal, the Department is required to specify basic requirements that providers must meet to be licensed. *See* Minn. Stat. § 245A.09, subd. 2 (listing basic standards that agency must address in rule). Although these requirements limit the flexibility that providers have in deciding how and where to provide care, these requirements also provide assurances to parents and families that a provider has met the health and safety standards specified by the Department.

In the current situation, however, one of the requirements enacted by the Department no longer protects the health and safety of those in care and, instead, actually prevents providers

from easily complying with current medical recommendations regarding treatment for poison ingestion. The most direct and least costly way to correct this problem is to repeal the syrup of ipecac requirement. Because this rulemaking involves the repeal of only one narrow licensing requirement, rather than the creation of new requirements, there was limited opportunity here to consider or implement performance-based standards. By repealing a rule requirement, however, the Department is giving licensed providers more flexibility and allowing them to more easily comply with the new medical recommendations governing the use of syrup of ipecac. This result comports with the goals of the legislative directive regarding performance-based rules.

### **ADDITIONAL NOTICE**

This Additional Notice Plan was reviewed by the Office of Administrative Hearings and approved in a January 4, 2006 letter by Administrative Law Judge Steve M. Mihalchick.

Our Additional Notice Plan consists of the following.

1. Publish the Notice of Intent to Adopt and the proposed rules in the State Register.
2. Mailing the Notice of Intent to Adopt and the proposed rules to people on the agency's registered rulemaking list under Minnesota Statutes, section 14.14, subdivision 1a.
3. Publishing the Notice of Intent to Adopt and proposed rules on the Department's website.
4. Sending copies of the Notice of Intent to Adopt, the proposed rules, and the Statement of Need and Reasonableness to the chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over child care and adult day care licensing as required in Minnesota Statutes, section 14.116.
5. Discussing the Notice of Intent to Adopt and proposed rules with the Minnesota Association of County Social Services Administrators Rules Committee.
6. Discussing the Notice of Intent to Adopt and proposed rules in regularly-scheduled communications with local licensing agencies and licensees.
7. Mailing the Notice of Intent to Adopt and proposed rules to licensed adult day services associations, licensed child care associations, and child care resource and referral organizations asking these groups to inform their members and the interested public of the proposed rulemaking.
8. Providing information to child care centers about the proposed rulemaking during the annual licensing process, which for the 2006 license began in September 2005.

We believe our Additional Notice Plan complies with the statute because it notifies persons or classes or persons who might be affected by the proposed rules. For example, county licensing agencies will receive notice through regularly-scheduled communications and meetings with the Department. Adult day services providers will receive notice through regularly-scheduled communications with the Department and through their professional association. Child care providers will receive notice through regularly-scheduled meetings with the Department and through their professional associations. Families using adult day services will receive notice through the Department website and through their providers. Finally, families using licensed child care providers will receive notice through the Department website, through the child care resource and referral agencies, and through their child care providers.

## CONSULT WITH FINANCE ON LOCAL GOVERNMENT IMPACT

As required by Minnesota Statutes, section 14.131, the Department has consulted with the Commissioner of Finance. We did this by sending to the Commissioner of Finance copies of the documents sent to the Governor's Office for review and approval by the Governor's Office prior to the Department publishing the Notice of Intent to Adopt. We sent the copies on December 27, 2005. The documents included: the Governor's Office Proposed Rule and SONAR Form; draft rules; and draft SONAR. The Department of Finance sent a letter dated January 5, 2006 with its comments.

The Department's evaluation of the fiscal impact and benefits of the proposed rules on local governments is described in the Regulatory Analysis section of this SONAR on pages 2-4.

## COST OF COMPLYING FOR SMALL BUSINESS OR CITY

### Agency Determination of Cost

As required by Minnesota Statutes, section 14.127, the Department has considered whether the cost of complying with the proposed rules in the first year after the rules take effect will exceed \$25,000 for any small business or small city. The Department has determined that the cost of complying with the proposed rules in the first year after the rules take effect will not exceed \$25,000 for any small business or small city. The Department has made this determination based on the probable costs of complying with the proposed rule, as described in the Regulatory Analysis section of this SONAR on pages 2-4.

## RULE-BY-RULE ANALYSIS

**Minnesota Rules, parts 9502.0435, subpart 7; 9503.0090, subpart 1; 9503.0125; 9503.0140, subpart 16; and 9555.9720, subpart 1.** It is necessary to amend these rules (1) to ensure that licensed child care and adult day services providers can protect the health and safety of those in their care by following the most recent medical recommendations regarding the use and retention of syrup of ipecac and (2) to ensure that licensed providers are not required to obtain or maintain unnecessary forms.

Medical authorities have determined that syrup of ipecac should no longer be used routinely as a poison treatment strategy. See Anthony S. Manoguerra et al., American Association of Poison Control Centers, Guideline on the Use of Ipecac Syrup in the Out-of-Hospital Management of Ingested Poisons (2004) (Attachment A) (hereinafter AAPCC Guidelines); Minnesota Poison Control System, Position Statement: Syrup of Ipecac Use in the Home (2005) (hereinafter MPCSS Statement); American Academy of Pediatrics Committee on Injury, Violence, and Poison Prevention, Policy Statement: Poison Treatment in the Home, 112 Pediatrics 1182 (2003) (hereinafter AAP Statement). Instead, caregivers should immediately call a poison control hotline when a person has ingested a toxic substance. MPCSS Statement, *supra* at 1. Medical authorities no longer recommend the use of syrup of ipecac because its effectiveness in preventing drug absorption has been demonstrated for only a few substances and clinical trials have not shown that administration of syrup of ipecac positively affects patient

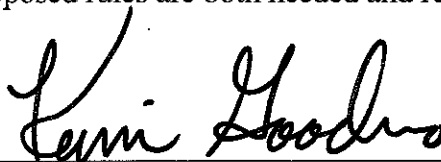
outcome. AAPCC Guidelines, *supra* at 2, 16-17; AAP Statement, *supra*. In addition, syrup of ipecac is an unpleasant therapy that causes persistent vomiting, which can delay or complicate the delivery of other proper therapies and/or create an increased risk of harm to the patient. AAPCC Guidelines, *supra* at 2, 17-20; AAP Statement, *supra*. Also, syrup of ipecac's other side effects, particularly lethargy, can mimic the effect of many poisons, which makes it more difficult for medical personnel to determine which poison was ingested. AAP Statement, *supra*. In short, because the potential harm related to the use of syrup of ipecac outweighs the benefits of this treatment, medical authorities now recommend that syrup of ipecac no longer be used by caregivers, that caregivers dispose of existing supplies of syrup of ipecac immediately or, at the very latest, when the expiration date is reached, and that caregivers refrain from buying new supplies of syrup of ipecac. AAPCC Guidelines, *supra*; MPCS Statement, *supra*; AAP Statement, *supra*.

Current licensing rules require licensed providers to keep syrup of ipecac on hand and, in the case of child care providers, obtain permission from parents to administer syrup of ipecac. As discussed above, however, medical authorities now recommend that caregivers no longer use syrup of ipecac as a poison treatment strategy and that caregivers no longer retain syrup of ipecac. To ensure that licensed providers can comply with these medical recommendations, it is reasonable to repeal the requirements in the licensing rules that require licensed child care and adult day services to keep syrup of ipecac in their first aid kits. Because providers will not be administering syrup of ipecac, it also is reasonable to repeal the rules requiring providers to notify parents that they must give permission for the provider to administer syrup of ipecac or to keep written forms giving them the authority to administer syrup of ipecac in children's files. The Department of Pediatrics at the University of Minnesota provided consultation and advice on the rule changes and supports the proposed changes.

## CONCLUSION

Based on the foregoing, the proposed rules are both needed and reasonable.

January 17, 2006

  
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Kevin Goodno  
Commissioner

## Bibliography

1. Anthony S. Manoguerra et al., American Association of Poison Control Centers, Guideline on the Use of Ipecac Syrup in the Out-of-Hospital Management of Ingested Poisons (2004) <http://www.aapcc.org/FinalizedPMGdlns/finalizedPMGuidelines.htm>
2. Minnesota Poison Control System, Position Statement: Syrup of Ipecac Use in the Home (2005) <http://www.mnpoison.org/index.asp?pageID=233>
3. American Academy of Pediatrics Committee on Injury, Violence, and Poison Prevention, Policy Statement: Poison Treatment in the Home, 112 Pediatrics 1182 (2003) <http://aappolicy.aappublications.org/cgi/content/full/pediatrics;112/5/1182#top>