OAH 8-0900-30570
Revisor RD 4101

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of the Proposed Rules of the Department of Health Governing School and Child Care Immunizations, *Minnesota Rules* Part 4604

REPORT OF THE ADMINISTRATIVE LAW JUDGE

This matter came before Administrative Law Judge Eric L. Lipman for a rulemaking hearing on June 27, 2013. The public hearing was held in Conference Room B-144 of the Minnesota Department of Health's main office in Saint Paul, Minnesota.

The Minnesota Department of Health (MDH or the Department) proposes to revise the timetable, structure and components of the state's immunization schedules. The Department's regulatory purpose is two-fold: MDH seeks to adjust the schedule and state immunization practice so as to align them with national standards. It also seeks to achieve high rates of immunization against a particular set of infectious diseases. As the Department reasons, if it can obtain immunization rates that meet or exceed 90 percent of the population, it will curb both the number of illnesses caused by these diseases and the ability of contagion to spread after any new outbreaks.[1]

Both the state's immunization schedule and the proposed adjustments are controversial. Many Minnesotans regard our state's immunization program as deeply flawed – and one that unwittingly produces serious, even life-threatening, outcomes for those who receive vaccines.[2]

The rulemaking hearing and this Report are part of a larger set of processes under the Minnesota Administrative Procedure Act.[3] The Minnesota Legislature has designed this process so as to ensure that state agencies have met all of the requirements that the state has specified for adopting rules.

The hearing was conducted so as to permit agency representatives and the Administrative Law Judge to hear public comment regarding the impact of the proposed rules and what changes might be appropriate. Further, the hearing process provides the general public an opportunity to review, discuss and critique the proposed rules.

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[1] Exhibit D at 8 – 10 and Attachment X. *See also,* Exs. R, S, U, V, X, Z and AA.

[2] *See, e.g.,* Ex. I (Comments Opposed to the Rule and Hearing Requests).

[3] *See,* Minn. Stat. §§ 14.131 through 14.20.

The agency must establish that the proposed rules are necessary and reasonable; that the rules are within the agency's statutory authority; and that any modifications that the agency may have made after the proposed rules were initially published in the *State Register* are within the scope of the matter that was originally announced.[4]

Nineteen people attended the hearing and signed the hearing register. The proceedings continued until all interested persons, groups or associations had an opportunity to be heard concerning the proposed rules. Each of the members of the public made statements or asked questions during the hearing.[5]

The agency panel at the public hearing included Patricia Segal-Freeman (Rule Coordinator, Minnesota Department of Health), Kristen Ehresmann (Director of the Division of Infectious Disease, Epidemiology, Prevention and Control, Minnesota Department of Health), Dr. Robert Jacobson (President of the Minnesota chapter of the American Academy of Pediatrics) and Dr. William Pomputius (a pediatric infectious disease specialist at Children's Hospitals and Clinics of Minnesota).[6]

After the close of the hearing, the Administrative Law Judge kept the rulemaking record open for another 20 calendar days – until Wednesday, July 17, 2013 – to permit interested persons and the Agency to submit written comments. Following the initial comment period, the hearing record was held open an additional five business days so as to permit interested parties and the Agency an opportunity to reply to earlier-submitted comments.[7] The hearing record closed on Wednesday, July 24, 2013.

On August 23, 2013, the Chief Administrative Law Judge granted an extension of three business days, until August 28, 2013, to complete this report.[8]

SUMMARY OF CONCLUSIONS

The Agency has established that it has the statutory authority to adopt the proposed rules, that it followed the required rulemaking procedures and that the proposed rules are needed and reasonable.

Based upon all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

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[4] Minn. Stat. §§ 14.05, 14.131, 14.23 and 14.25.

[5] HEARING REGISTER, at 1- 4; HEARING TRANSCRIPT, at 2 (June 27, 2013).

[6] HEARING TRANSCRIPT, at 17 – 56.

[7] *See,* Minn. Stat. § 14.15, subd. 1.

[8] Minn. Stat. § 14.15, subd. 2.

FINDINGS OF FACT

I. Regulatory Background to the Proposed Rules

In 1967, the Minnesota Legislature enacted the Minnesota School Immunization law.[9] The law requires that parents or guardians provide schools and child care facilities with documentation relating to the immunization of their children. The documentation must reflect either completion of the required immunizations "according to medically acceptable standards," or that one of the exemptions from immunization practice applies.[10] No person older than two-months old may remain enrolled in an elementary school, secondary school or child care facility without furnishing the required disclosures.[11]

Beginning in 1980, and periodically thereafter, the Legislature added to the disclosure requirements strictures as to dosages for particular vaccines. The Legislature provided that the disclosures were "acceptable" only if they reflected that certain dosages of vaccines were administered within particular age ranges.[12] In this way, the Legislature set, and updated, declarations as to the minimum prevailing standards for vaccines.

In 2002, the Legislature conferred a special – and arguably unique – set of regulatory powers upon the Department. The Department was permitted to periodically adjust the "acceptable" regimen of vaccine dosages that had been placed into statute, provided that the Department made those changes through a set of specialized and more rigorous rulemaking requirements.[13] With this delegation, the Department was charged with updating state immunization practice to reflect, and keep pace with, changes in national vaccine administration recommendations.[14]

Characterizing the current vaccine practice standards as "outdated," the Department seeks to update the state's immunization schedule in this proceeding.[15]

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[9] *See,* Minn. Stat. § 121A.15.

[10] Minn. Stat. § 121A.15, subds. 1 and 3.

[11] Minn. Stat. § 121A.15, subd. 1.

[12] *See, e.g.,* 1980 Laws of Minnesota, Chapter 504, Section 1; 1988 Laws of Minnesota, Chapter 430, Section 2.

[13] *See,* 2001 Laws of Minnesota, 1st Special Session, Chapter 9, Article 1, Section 25; 2002 Laws of Minnesota, Chapter 379, Article 1, Section 113.

[14] Minn. Stat. § 121A.15, subd. 12 (a) ("A proposed modification made under this subdivision must be part of the current immunization recommendations of each of the following organizations: the United States Public Health Service's Advisory Committee on Immunization Practices, the American Academy of Family Physicians, and the American Academy of Pediatrics").

[15] *See,* Ex. D at 1, 19 and 20.

II. Rulemaking Authority

1. The Agency cites Minn. Stat. § 121A.15, subd. 12 as its source of statutory authority for these proposed rules.[16]

2. Because, as noted above, this statute imposes specialized conditions upon the promulgation of rules that adjust the state "immunization requirements" under Minn. Stat. § 121A.15, the particulars of that statute are set out, at length, below. Subdivision 12 of Minn. Stat. § 121A.15 provides in relevant part:

> (a) The commissioner of health may adopt modifications to the immunization requirements of this section. A proposed modification made under this subdivision must be part of the current immunization recommendations of each of the following organizations: the United States Public Health Service's Advisory Committee on Immunization Practices, the American Academy of Family Physicians, and the American Academy of Pediatrics. In proposing a modification to the immunization schedule, the commissioner must:
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> > (1) consult with (i) the commissioner of education; the commissioner of human services; the chancellor of the Minnesota State Colleges and Universities; and the president of the University of Minnesota; and (ii) the Minnesota Natural Health Coalition, Vaccine Awareness Minnesota, Biological Education for Autism Treatment (BEAT), the Minnesota Academy of Family Physicians, the American Academy of Pediatrics-Minnesota Chapter, and the Minnesota Nurses Association; and
> >
> > (2) consider the following criteria: the epidemiology of the disease, the morbidity and mortality rates for the disease, the safety and efficacy of the vaccine, the cost of a vaccination program, the cost of enforcing vaccination requirements, and a cost-benefit analysis of the vaccination.
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> (b) Before a proposed modification may be adopted, the commissioner must notify the chairs of the house of representatives and senate committees with jurisdiction over health policy issues. If the chairs of the relevant standing committees determine a public hearing regarding the proposed modifications is in order, the hearing must be scheduled within 60 days of receiving notice from the commissioner. If a hearing is scheduled, the commissioner may not adopt any proposed modifications until after the hearing is held.

[16] Ex. D at 1, 19 and 20.

(c) The commissioner shall comply with the requirements of chapter 14 regarding the adoption of any proposed modifications to the immunization schedule.[17]

3. The proposed modifications to the state's immunization requirements are in accord with the current immunization recommendations of:

(a) the United States Public Health Service's Advisory Committee on Immunization Practices;[18]

(b) the American Academy of Family Physicians;[19] and

(c) the American Academy of Pediatrics.[20]

4. When developing its proposed rules, the Department undertook a wide range of consultations. It consulted:

(a) the Commissioner of Education;[21]

(b) the Chancellor of the Minnesota State Colleges and Universities;[22]

(c) the President of the University of Minnesota;[23]

(d) the Minnesota Natural Health Coalition;[24]

(e) Vaccine Awareness Minnesota;[25]

(f) Biological Education for Autism Treatment (BEAT);[26]

(g) the Minnesota Academy of Family Physicians;[27]

(h) the American Academy of Pediatrics - Minnesota Chapter;[28] and

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[17] Minn. Stat. § 121A.15 (emphasis added).

[18] Ex. D at 19.

[19] Ex. D at 19 and Attachments B and F.

[20] Ex. D at 15 and Attachments B and F.

[21] Ex. D at 4.

[22] *Id*.

[23] *Id*.

[24] Ex. D at 4 and Attachment C.

[25] *Id*.

[26] *Id*.

[27] Ex. D, Attachment C.

(i) the Minnesota Nurses Association.[29]

5. When developing its proposed rules, the Department notified the chairs of the committees with "jurisdiction over health policy issues" in the Minnesota House of Representatives and the Minnesota Senate.[30]

6. Neither committee convened a hearing on the proposed rules within 60 days of receiving notice of this rulemaking proceeding.[31]

7. As detailed in *Section III* below, the Department complied with the procedural requirements of Chapter 14 regarding the adoption of any proposed modifications to the immunization schedule.

8. Anne Tenner, of National Health Freedom Action, asserted that notwithstanding the statutory exemption from immunization for those who decline vaccines because of their "conscientiously held beliefs," the proposed rules violate the due process guarantee of the Fourteenth Amendment.[32]

9. The Administrative Law Judge determines that *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905), leads to a different conclusion. In that case, Henning Jacobson argued that a Massachusetts law which obliged all adults to be vaccinated against smallpox – and threatened imprisonment or a fine for those who refused to be vaccinated – violated the liberty guarantees of the Fourteenth Amendment. The Supreme Court disagreed. The Court concluded that the Massachusetts law was directed at an important public health purpose and would only violate the liberty guarantees of the Fourteenth Amendment if one of two circumstances were present: (a) the statute "purporting to have been enacted to protect the public health, the public morals, or the public safety, has no real or substantial relation to those objects"; or (b) the statute "is, beyond all question, a plain, palpable invasion of rights secured by the fundamental law."[33] As Justice Harlan explained:

> Whatever may be thought of the expediency of this statute, it cannot be affirmed to be, beyond question, in palpable conflict with the Constitution. Nor, in view of the methods employed to stamp out the disease of smallpox, can anyone confidently assert that the means prescribed by the state to that end has no real or substantial relation to the protection of the public health and the public safety. Such an assertion would not be

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[28] Ex. D, Attachments C, E and I.

[29] Ex. D at 4.

[30] Ex. K.

[31] See, On-Line Minutes of the House Health and Human Services Policy Committee and Senate Health, Human Services and Housing Committee (2013).

[32] *Compare,* HEARING TRANSCRIPT, at 141-46; Ex. AM with Minn. Stat. § 121A.15, subd. 3.

[33] *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 31 (1905).

> consistent with the experience of this and other countries whose authorities have dealt with the disease of smallpox. And the principle of vaccination as a means to prevent the spread of smallpox has been enforced in many states by statutes making the vaccination of children a condition of their right to enter or remain in public schools.
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> ….
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> Since, then, vaccination, as a means of protecting a community against smallpox, finds strong support in the experience of this and other countries, no court, much less a jury, is justified in disregarding the action of the legislature simply because in its or their opinion that particular method was-perhaps, or possibly-not the best either for children or adults.[34]

The Administrative Law Judge concludes that the legal tests announced in *Jacobson* are not met here. The proposed rules do have a "substantial relation" to the object of preserving public health,[35] and given the wide-ranging exemptions that can be claimed by those who do not wish to be vaccinated, the proposed rules do not result in "a plain, palpable invasion of rights secured by the fundamental law."[36] If Massachusetts' compulsory vaccination program did not offend the liberty guarantees of the Fourteenth Amendment, Minnesota's more modest program of compulsory disclosures does not abridge these same guarantees.[37]

10. For all of these reasons, the Administrative Law Judge concludes that the Agency has the legal authority to adopt the proposed rules.

III. Procedural Requirements of Chapter 14

A. Publication and Filings

11. On April 30, 2012, the Department published in the *State Register* a Request for Comments seeking comments on possible amendments to the state's immunization requirements.[38]

12. On April 4, 2013, the Department filed documents with the Office of Administrative Hearings seeking review and approval of its Notice of Intent to Adopt Rules With or Without a Hearing (Dual Notice) and its additional notice plan. By way of

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[34] *Id.* at 33.

[35] *Compare,* Ex. C with Exs. D, I, L, Q, R, S, T, U, V, W and X.

[36] *Jacobson*, 197 U.S. at 31.

[37] *Id.* at 31-35; *accord, Zucht v. King,* 260 U.S. 174, 176 (1922) ("Long before this suit was instituted, *Jacobson v. Massachusetts*, 197 U.S. 11 … had settled that it is within the police power of a state to provide for compulsory vaccination").

[38] 36 *State Register* 1297 (April 30, 2012).

an Order dated April 11, 2013, the Dual Notice and additional notice plan were approved.[39]

13. The Dual Notice of Intent to Adopt Rules, published in the April 29, 2013 *State Register*, set Friday, May 31, 2013 as the deadline for comments or to request a hearing.[40]

14. On April 26, 2013, the Department mailed a copy of the Dual Notice of Hearing to all persons and associations which had registered their names with the Department for the purpose of receiving such notice. On April 29, 2013, MDH sent electronic notices to the persons and associations listed in the additional notice plan.[41]

15. On April 29, 2013, the Department mailed a copy of the Dual Notice and the Statement of Need and Reasonableness (SONAR) to the chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over environmental regulation.[42]

16. On April 29, 2013, the Department mailed a copy of the SONAR to the Legislative Reference Library to meet the requirement set forth in Minn. Stat. §§ 14.131 and 14.23.[43]

17. The Notice of Hearing identified the date and location of the hearing in this matter.[44]

18. At the hearing on June 27, 2013, the Department placed into the hearing record the documents required by Minn. R. 1400.2220.[45]

B. Additional Notice Requirements

19. Minn. Stat. §§ 14.131 and 14.23 requires that an agency include in its SONAR a description of its efforts to provide additional notification to persons or classes of persons who may be affected by the proposed rule; or alternatively, the agency must detail why these notification efforts were not made.

20. On April 29, 2013, the Department provided the Dual Notice of Intent to Adopt in the following manner, according to the Additional Notice Plan approved by the Office of Administrative Hearings:

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[39] ORDER ON REVIEW OF ADDITIONAL NOTICE PLAN AND DUAL NOTICE, OAH 8-0900-30570 (April 11, 2013).

[40] Ex. F.

[41] Exs. G and H.

[42] Ex. K.

[43] Ex. E.

[44] Ex. F.

[45] *See,* Exs. A, C, D, E, F, G, H, I and K.

- The Dual Notice of Intent to Adopt Rules was posted on the Department's website and the Department has maintained these materials continuously since they were posted.

- Notice of the rulemaking was sent by first class mail to the notice list the Department maintains pursuant to Minn. Stat. § 14.14.

- A copy of the Dual Notice of Intent to Adopt and the proposed rules were sent by electronic mail to a wide-ranging set of public health organizations, health advocacy groups and associations of medical practitioners, as detailed in its Additional Notice Plan.

- Notice of the rulemaking was circulated through advisories by the Department to the news media and postings to the Department's Facebook and Twitter accounts.

- Agency staff included notice of the rulemaking in a number of public presentations that were made to stakeholders.[46]

C. Notice Practice

21. The Administrative Law Judge concludes that the Department fulfilled its responsibilities under Minn. R. 1400.2080, subp. 6, to mail the Dual Notice "at least 33 days before the end of the comment period" to potential stakeholders.[47]

22. The Administrative Law Judge concludes that the Department fulfilled its responsibilities to mail the Dual Notice "at least 33 days before the end of the comment period" to designated legislators.[48]

23. The Administrative Law Judge concludes that the Department fulfilled its responsibilities to mail the Dual Notice "at least 33 days before the end of the comment period …."[49]

D. Impact on Farming Operations

24. Minn. Stat. § 14.111 imposes additional notice requirements when the proposed rules affect farming operations. The statute requires that an agency provide a copy of any such changes to the Commissioner of Agriculture at least 30 days prior to publishing the proposed rules in the *State Register*.

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[46] Ex. H.

[47] Ex. G and H.

[48] Ex. K; *see also,* Minn. Stat. § 14.116.

[49] Ex. K; *see also,* Minn. Stat. § 14.23.

25. The proposed rules do not impose restrictions or have an impact on farming operations. The Administrative Law Judge finds that the Department was not required to notify the Commissioner of Agriculture.

E. Statutory Requirements for the SONAR

26. The Administrative Procedure Act obliges an agency adopting rules to address seven factors in its Statement of Need and Reasonableness.[50] Those factors are:

> (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;
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> (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;
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> (3) a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;
>
> (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;
>
> (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;
>
> (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; and
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> (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.

[50] Minn. Stat. § 14.131.

1. The Agency's Regulatory Analysis

(a) 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.

27. The Department asserts that the proposed rule will benefit a wide-range of persons – including pre-school and school-aged children; parents of those children; health care providers; health insurance companies; and the general public. These benefits will accrue, continues the Department, by aligning immunization practices in Minnesota with nationally-recognized standards and simplifying the collection of immunization-related data.[51]

(b) 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.

28. The Department projects that implementation of the proposed rules will result in modest new costs to the Department – all of which are associated with updating educational materials that it distributes to health care providers, schools, child care facilities and the general public. The Department plans to address any rule changes as part of its regular process for updating the educational materials.[52]

29. The Department likewise asserts that adoption of the proposed rules will not increase the costs incurred by sister agencies. The Department projects that the addition of new vaccines to the disclosure requirements will not increase program costs for the licensing agencies that review this data. Indeed, both the Minnesota Department of Human Services and the Minnesota Department of Education (MDE) expressed support for the proposed rules.[53]

30. Lastly, the Department does not forecast any changes to state revenues following adoption of the proposed rules. Both the Minnesota Health Care Programs (MHCP) and Minnesota Vaccines for Children (MnVFC) program now provide immunizations according to the recommendations of the federal Advisory Committee on Immunization Practices (ACIP) – including those in the proposed rules.[54]

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[51] Ex. D at 5-8.

[52] *Id.* at 8.

[53] *Id*.

[54] *Id*.

(c) The determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

31. The Department considered regulatory alternatives to the proposed rules.[55]

32. The Department asserts that repealing the existing requirements, and instead relying upon health care providers to immunize patients at their next convenience, would "expose many children to vaccine-preventable disease." The Department maintains that the definite, evidence-based timelines set forth in the proposed rules contribute to public health.[56]

33. For these reasons, the Department asserts that the proposed rules represent the least costly method of achieving the purposes of the proposed rules. Likewise, because of the wide-ranging set of exemptions under the state's immunization law, the Department argues that the proposed rules represent the least intrusive method of achieving the purposes of the state immunization program.[57]

(d) 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.

34. The Department considered, and rejected, reliance upon a public education campaign in place of the proposed rules.

35. In addition to placing added costs on to state agencies and local educations systems, the Department concluded that a public education campaign was unlikely to yield similar, high rates of immunization. Accordingly, to the extent that substituting a media campaign for the proposed rules would be followed by significant new outbreaks of preventable-disease, the Department excluded this option as too costly and burdensome.[58]

36. The Department maintains that the proposed rules are the best method of achieving the purposes of the state immunization program.[59]

(e) The probable costs of complying with the proposed rules.

37. The Department projects that implementation of the proposed rules will result in modest compliance costs, if any additional costs at all. This is because the

[55] *Id.* at 9-10.

[56] *Id.* at 9; Ex. T; Ex. V.

[57] Ex. D at 9.

[58] *Id.* at 9; Ex. T.

[59] Ex. D at 9-10.

savings that are associated with streamlining the reporting of immunization information, and the alignment to widespread immunization practices, will offset or exceed the costs that are associated with receiving additional vaccine-related data.[60]

(f) The probable costs or consequences of not adopting the proposed rule, including those costs borne by individual categories of affected parties, such as separate classes of governmental units, businesses, or individuals.

38. The Department asserts that the consequences of not adopting the proposed rules will result in more severe disease outbreaks, higher rates of sickness and death, and additional costs to treat the illnesses that do occur.[61]

39. The Department points to the costs of the 2012 outbreak of pertussis (whooping cough) in Minnesota. In that instance, there were 4,400 reported cases of the disease. In 52 of the more serious cases, the disease prompted hospitalization of the infected persons. These costs, continues the Department, burden the individuals involved, health care providers, insurers and the community at large.[62]

(g) An assessment of any differences between the proposed rules and existing federal regulation and a specific analysis of the need for and reasonableness of each difference.

40. The Department asserts that immunization practice is, traditionally, a state function and that there are no applicable federal rules.[63]

(h) An assessment of the cumulative impact of state and federal regulations on this topic.

41. The proposed rules supplant the only existing regulation on immunization in schools and child-care facilities. Moreover, representatives from the regulated industries supported the proposed rules.[64]

2. Performance-Based Regulation

42. The Administrative Procedure Act[65] also requires an agency to describe how it has considered and implemented the legislative policy supporting performance based regulatory systems. A performance based rule is one that emphasizes superior

[60] *Id.* at 10-11.

[61] *Id.* at 11-12.

[62] *Id.* at 12.

[63] *Id*.

[64] *Id*. at 8, 11, Attachment E and Attachment I.

[65] Minn. Stat. § 14.131.

achievement in meeting the agency's regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals.[66]

43. The Department asserts that the proposed rules yield superior achievement and maximum flexibility because they will achieve high rates of immunization, ease some reporting requirements and generous exemptions for medical reasons or highly individualized reasons.[67]

3. Consultation with the Commissioner of Minnesota Management and Budget (MMB)

44. As required by Minn. Stat. § 14.131, by letter dated January 28, 2013, the Commissioner of Minnesota Management and Budget (MMB) responded to a request by the Department to evaluate the fiscal impact and benefit of the proposed rules on local units of government. MMB reviewed the Agency's proposed rules and concluded that these "rule changes will have a minimal fiscal impact on local governments."[68]

4. Cost to Small Businesses and Cities under Minn. Stat. § 14.127

45. Minn. Stat. § 14.127, requires the Department to "determine if the cost of complying with a proposed rule in the first year after the rule takes effect will exceed $25,000 for: (1) any one business that has less than 50 full-time employees; or (2) any one statutory or home rule charter city that has less than ten full-time employees." The Department must make this determination before the close of the hearing record, and the Administrative Law Judge must review the determination and approve or disapprove it.[69]

46. The Department determined that because the cost of any vaccine referenced in the proposed rules is most often borne by either an individual, or that individual's health insurer, the cost of complying with the proposed rule changes will not exceed $25,000 for any business or any statutory or home rule charter city.[70]

5. Adoption or Amendment of Local Ordinances

47. Under Minn. Stat. § 14.128, the Department must determine if a local government will be required to adopt or amend an ordinance or other regulation to comply with a proposed agency rule. The Department must make this determination

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[66] Minn. Stat. § 14.002.

[67] Ex. D at 12-13.

[68] Ex. K.

[69] Minn. Stat. § 14.127, subds. 1 and 2.

[70] Ex. K.

before the close of the hearing record, and the Administrative Law Judge must review the determination and approve or disapprove it.[71]

48. The Department concluded that no local government will need to adopt or amend an ordinance or other regulation to comply with the proposed rules. The Department's proposed rule should not require local governments to adopt or amend those more general ordinances and regulations.[72]

49. The Administrative Law Judge finds that the Department has made the determination required by Minn. Stat. § 14.128 and approves that determination.

6. Required Elements of the SONAR

50. The Administrative Law Judge finds that the Department has met the requirements for assessing the impact of the proposed rules, including consideration and implementation of the legislative policy supporting performance-based regulatory systems, and the fiscal impact on units of local government.

51. The Administrative Law Judge finds that the Department has made the cost determinations required by Minn. Stat. § 14.127 and approves those determinations.

52. The Administrative Law Judge finds that the Department has met its obligations under Minn. Stat. § 14.131.

IV. Rulemaking Legal Standards

53. The Administrative Law Judge must make the following inquiries: Whether the agency has statutory authority to adopt the rule; whether the rule is unconstitutional or otherwise illegal; whether the agency has complied with the rule adoption procedures; whether the proposed rule grants undue discretion to government officials; whether the rule constitutes an undue delegation of authority to another entity; and whether the proposed language meets the definition of a rule.[73]

54. Under Minn. Stat. § 14.14, subd. 2, and Minn. R. 1400.2100, the agency must establish the need for, and reasonableness of, a proposed rule by an affirmative presentation of facts. In support of a rule, the agency may rely upon materials developed for the hearing record,[74] "legislative facts" (namely, general and well-established principles, that are not related to the specifics of a particular case, but which

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[71] Minn. Stat. § 14.128, subd. 1. Moreover, a determination that the proposed rules require adoption or amendment of an ordinance may modify the effective date of the rule, subject to some exceptions. Minn. Stat. § 14.128, subds. 2 and 3.

[72] Ex. D at 15.

[73] *See,* Minn. R. 1400.2100.

[74] *See, Manufactured Housing Institute v. Pettersen*, 347 N.W.2d 238, 240 (Minn. 1984); *Minnesota Chamber of Commerce v. Minnesota Pollution Control Agency*, 469 N.W.2d 100, 103 (Minn. Ct. App. 1991).

guide the development of law and policy),[75] and the agency's interpretation of related statutes.[76]

55. A proposed rule is reasonable if the agency can "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken."[77] By contrast, a proposed rule will be deemed arbitrary and capricious where the agency's choice is based upon whim, devoid of articulated reasons or "represents its will and not its judgment."[78]

56. An important corollary to these standards is that when proposing new rules the Department is entitled to make choices between different possible regulatory approaches, so long as the alternative that is selected by the agency is a rational one.[79] This is because the delegation of rulemaking authority runs from the Minnesota Legislature to the agency, and not to the Administrative Law Judge.[80]

57. For this reason, the Administrative Law Judge does not "vote" for particular vaccine policies or select those vaccine measures that the Judge considers to be in the best interest of the public.

58. During a legal review of proposed rules, the role of the Administrative Law Judge is to determine whether the Department has made a reasonable selection among the regulatory options it had. Thus, while reasonable minds might differ as to whether one or another approach represents "the best alternative," the agency's selection will be approved if it is one that a rational person could have made.[81]

59. Lastly, because the Administrative Law Judge suggests one editorial change to the proposed rule language (and this suggestion comes after the language was published by the Department in the *State Register*), it is also necessary to determine if this language is substantially different from that which was originally proposed. This suggested change is discussed below in Section VI of this report. The standards to determine whether any changes to proposed rules create a substantially different rule are found in Minn. Stat. § 14.05, subd. 2. The statute specifies that a modification does not make a proposed rule substantially different if:

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[75] *Compare generally, United States* v. *Gould,* 536 F.2d 216, 220 (8th Cir. 1976).

[76] *See, Mammenga v. Agency of Human Services*, 442 N.W.2d 786, 789-92 (Minn. 1989); *Manufactured Hous. Inst.*, 347 N.W.2d at 244.

[77] *Manufactured Hous. Inst.*, 347 N.W.2d at 244.

[78] *See, Mammenga*, 442 N.W.2d at 789; *St. Paul Area Chamber of Commerce v. Minn. Pub. Serv. Comm'n*; 251 N.W.2d 350, 357-58 (Minn. 1977).

[79] *Peterson v. Minn. Dep't of Labor & Indus*., 591 N.W.2d 76, 78 (Minn. Ct. App. 1999).

[80] *See,* REPORT OF THE ADMINISTRATIVE LAW JUDGE, *In the Matter of the Proposed Rules of the Minnesota Pollution Control Agency Governing Permits for Greenhouse Gas Emissions, Minnesota Rules Chapters 7005, 7007 and 7011*, OAH 8-2200-22910-1 at 20 (2012) (http://mn.gov/oah/images/2200-22910-GreenhouseGas-dismissal.pdf).

[81] *See, Minnesota Chamber of Commerce*, 469 N.W.2d at 103.

"the differences are within the scope of the matter announced . . . in the notice of hearing and are in character with the issues raised in that notice";

the differences "are a logical outgrowth of the contents of the . . . notice of hearing, and the comments submitted in response to the notice"; and

the notice of hearing "provided fair warning that the outcome of that rulemaking proceeding could be the rule in question."

60. In reaching a determination regarding whether modifications result in a rule that is substantially different, the Administrative Law Judge is to consider:

whether "persons who will be affected by the rule should have understood that the rulemaking proceeding . . . could affect their interests;"

whether the "subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the . . . notice of hearing;" and,

whether "the effects of the rule differ from the effects of the proposed rule contained in the . . . notice of hearing."[82]

V. Rule Analysis

A. Vaccine Safety

61. In this case, a key dispute was whether any requirement that encouraged wide-spread use of the listed vaccines was needed and reasonable. As the rule opponents argued, the health impacts associated with vaccines against diphtheria,[83] hepatitis A and B,[84] measles,[85] mumps,[86] pertussis,[87] polio,[88] rubella,[89] tetanus,[90] meningitis[91] and varicella,[92] render large-scale administration of these compounds unsafe and unreasonable.

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[82] *See,* Minn. Stat. § 14.05, subd. 2.

[83] *See,* Exs. AB, AG; AT and BL.

[84] *See,* Exs. AB, AG; AH, AI, AN, AO, AS, AW, AY, BF, BI and BN; HEARING TRANSCRIPT, at 62.

[85] *See,* Exs. AA, AB and BN.

[86] *See,* Exs. AZ, BF and BN.

[87] *See,* Exs. AB, AG, AT and BL.

[88] *See,* AB, AG, AT, BF and BN.

[89] *See,* Exs. BA, BF and BN.

[90] *See,* Exs. AB, AG, AT, BF and BL.

[91] *See,* Ex AB.

[92] *See,* Exs. AA, BF and BN.

62. The health impacts that the rule opponents link to vaccine administration are very grave. The accounts of genuine suffering, particularly among young people, are heart-breaking. This suffering could never be adequately or completely described here.[93]

63. In this proceeding, however, the question is not whether vaccines caused the injuries that are described in the record. This proceeding does not, and frankly could not, establish that the listed vaccines caused the injuries that were described.[94]

64. Instead, given that the Minnesota Legislature has determined that collecting immunization-related data serves a useful public purpose, the question for this proceeding is whether the revisions that the Department now proposes to the current schedules and practices are needed and reasonable.[95]

65. The Administrative Law Judge finds that the Department has demonstrated by an affirmative presentation of facts the need for and reasonableness of the proposed immunization and disclosure requirements relating to diphtheria,[96] hepatitis A and B,[97] measles,[98] mumps,[99] pertussis,[100] polio,[101] rubella,[102] tetanus,[103] meningitis[104] and varicella.[105]

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[93] *See, e.g., Comments of Chris Abel* (stories of Eddie I. and Bryan K. and "Cassandra Threads"); *Comments of Kate Birsch; Comments of Patti Carroll; Comments of Leo B. Cashman; Comments of Paul Groshen* (Ian Gromowski's story); *Comments of Nancy Hokkanen; Comments of Jerri Johnson* (Lyla Rose Belkin's story); *Comments of Judy Joseph; Comments of Jennifer Larson; Comments of Karen Schultz;* HEARING TRANSCRIPT, at 61 – 65, 96-108, 113-17, 135, 163-66 and 182.

[94] *See, Jacobson*, 197 U.S. at 31 (As to the propriety of vaccinating against disease "no court, much less a jury, is justified in disregarding the action of the legislature simply because in its or their opinion that particular method was-perhaps, or possibly-not the best either for children or adults"); *But compare, Rebuttal Comments of the National Health Freedom Center,* at 1 (The evidence of a causal connection between vaccine administration and the injuries described in the hearing record is "overwhelming and undeniable"); HEARING TRANSCRIPT, at 103-04 ("The government never disputed the cause of injury for my child, which makes us a very lucky family. That normally never happens. Immediately they came back and said: 'Yes, we agree, your child was vaccine-injured'").

[95] *Compare,* Minn. Stat. § 14.14, subd. 2 with Minn. Stat. § 121A.15, subd. 12.

[96] *See,* Ex. D at 20 and 38-44; Exs. T and W.

[97] *See,* Ex. D at 23-38; Exs. Y and Z.

[98] *See,* Ex. D at 21; Ex. AA.

[99] *Id*.

[100] *See,* Ex. D at 38-44 and Attachment F; Exs. T, W and Y.

[101] *See,* Ex. D at 19.

[102] *See,* Ex. D at 20; Exs. T, W and AA.

[103] *See,* Ex. D at 20 and 38-44; Exs. T and W.

[104] *See,* Ex. D at 44-52; Ex. Y.

[105] *See,* Ex. D at 21-22; Exs. X and Z.

B. Additions to the Current Practice

66. The Administrative Law Judge finds that the Department has demonstrated by an affirmative presentation of facts the need for and reasonableness of the proposed definition of "medically acceptable standards" in Minn. R. 4604.0200, subd. 2a. The immunization recommendations referenced in the proposed rule are published by the Centers for Disease Control and Prevention (CDC) following approval from the federal Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP). Moreover, once approved, the recommendations are redistributed by state health departments and medical associations to health care providers. Thus, the cited recommendations are sufficiently definite, grounded in appropriate science and "conveniently available to the public" so as to constitute a proper rule.[106]

67. The Administrative Law Judge finds that the Department has demonstrated by an affirmative presentation of facts the need for and reasonableness of the proposed extension of immunization and disclosure requirements to child-care facilities. The Department established a reasonable basis to believe that extending the immunization and disclosure requirements to child care facilities will lead to reductions in preventable diseases, improve program administration and avoid significant costs to medical assistance and special education programs in the state.[107]

C. Other Actions Urged By Stakeholders

68. During the rulemaking hearing, and thereafter during the public comment period, there were two other important critiques of the proposed rules – namely that the proposed immunization schedule did not encourage the spacing, over time, of different immunizations and the exemption provisions of the law are not made clear in MDH's "Pupil Immunization Record" form.[108] Each of these critiques is addressed below.

1. Encouraging New Patient-Centered Immunization Options

69. At the rulemaking hearing, several commentators argued that the proposed rules do not do enough to encourage individualized health care decisions – instead pressuring parents to accede to a schedule that was set for the entire country. For example, as A.J. Paron-Wildes, founder of Biological Education for Autism Treatments (BEAT) noted at the hearing:

> It's very difficult to find a doctor that won't do the mandated schedule; that is willing to go off of a different schedule, to do something that's a little more unique for that child. It's very hard to find people that are willing to compromise. And I think that's a lot of the answer here, is that it can't be a

[106] *See,* Ex. D at 1, 6 and 8; Ex. D at Attachments B and F.

[107] *See,* Ex. D at 1, 9, 10, 11, 17-19; Exs. V, X and Z.

[108] *See,* Ex. AK.

> one size fits all. It needs to be something that is person-centered. Instead of just evidence-based, it has to turn into something that's person centered for that individual. I've had a personal family member, a cousin who has both glutathione and she has autoimmune disorders. And when she decided – she was vehement to not vaccinate her child. And when she went in for the three-year-old checkup, not only did her doctor come in, but that doctor brought in other doctors and sat there and chastised her and wouldn't – Basically she said she couldn't leave until she vaccinated her child. She was in tears in front of the doctor.
>
> So, you know, it's a challenge because this perception of mandating, a lot of people feel they don't have a choice. Even though I understand it's on the form, many times those conversations you aren't talking about a form. You're not looking at a form, you're talking to your doctor.
>
> ….
>
> And we need to send a message to the doctor that they can do something different than that mandated schedule if that's in the best interest of their child. And I think that's something that has not really been addressed.[109]

70. While Ms. Paron-Wildes's suggestion is an eminently useful one – and one that should be of interest to state policymakers – in this context it does not demonstrate that MDH's chosen approach is based upon whim or is devoid of articulated reasons. To the contrary, both the Legislature and the Department have thought carefully about the benefits of aligning Minnesota's practice with the recommendations of the Advisory Committee on Immunization Practices.[110]

2. Phrasing and Placement of the Exemption Attestations

71. At the rulemaking hearing, several commentators asserted that the proposed rules do not do enough to apprise parents of the medical and conscience exemptions that are available to them under Minnesota law. For example, as Kathryn Loeb testified:

> I want to see the conscientious objector be as bold and as out and on the open alongside this recommendation to parents, especially those that don't know. Right now it's kind of hidden on the back side of the form and it should be on the front side of the form so people can make a decision. One other thing is that before people sign off, they should see what these ingredients are that they're injecting into their children at the doctor's office. They shouldn't just say: "Yep, I'm getting vaccinated."[111]

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[109] HEARING TRANSCRIPT, at 181-83; *see also,* HEARING TRANSCRIPT, at 63, 67, 135, 139, and 142.

[110] *See generally,* Exhibit D at 8 – 10 and Attachment X; Exs. R, S, U, V, X, Z and AA.

[111] HEARING TRANSCRIPT, at 67; *see also,* HEARING TRANSCRIPT, at 65, 159, 182-83.

72. Ms. Loeb's suggestion is also a very useful one, but for several reasons, it does not signify a legal defect in the proposed rules.

73. There is real doubt that citizens have a legal right to insist that a state agency use a particular form when the agency carries out official duties.[112]

74. The Department has promulgated rules on the exemption forms, but those rules are not the subject of this proceeding.[113] The Administrative Law Judge concludes that maintaining the "Pupil Immunization Record," without any revision, does not show that the rules proposed here are unreasonable.

D. Summary

75. The Administrative Law Judge finds that the Department has demonstrated by an affirmative presentation of facts the need for and reasonableness of all rule provisions that are not specifically addressed in this Report.

76. Further, the Administrative Law Judge finds that all provisions that are not specifically addressed in this Report are authorized by statute and that there are no other defects that would bar the adoption of those rules.

VI. Recommended Technical Correction: Minn. R. 4604.0200

77. The Administrative Law Judge recommends one technical change to the proposed rules. A technical correction is not a defect in the proposed rule, but rather a recommendation that the Department may adopt, if it sees fit, so as to aid in the administration of the rule.

78. The Administrative Law Judge recommends an editorial change in proposed rule so as to make the proposed rule easier to read. The first sentence of proposed Minn. R. 4604.0200 should be revised to delete the words "at the national level." These words do not qualify, restrict or lend meaning to the proposed rule.

79. The change recommended above is needed and reasonable and would not be a substantial change from the rules as proposed.

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[112] *In the Matter of Leisure Hills Health Care Center*, a nursing care facility licensed by the Minnesota Department of Health complained that the agency's methods of carrying out nursing home inspections should be subject to the rulemaking requirements of the Minnesota Administrative Procedures Act. Disagreeing, the appellate panel held that the methods by which the agency inspected a licensee's performance were exempt from rulemaking under Minn. Stat. § 14.03, subd. 3(1). As the panel observed: "[T]he Department's procedures do not directly affect the rights of the public. The Department has promulgated its substantive standards in accordance with the Minnesota APA…. The inspection procedures by which the Department enforces the substantive standards, however, do not directly affect Leisure Hills' rights." *In re Leisure Hills Health Care Center*, 518 N.W.2d 71, 74-75 (Minn. Ct. App.) *review denied* (Minn. 1994).

[113] *Compare,* Minn. R. 4604.0400 with Ex. C at 1 (Revisor RD 4101).

Based upon the Findings of Fact and the contents of the rulemaking record, the Administrative Law Judge makes the following:

CONCLUSIONS

1. The Department gave notice to interested persons in this matter.

2. The Administrative Law Judge concludes that the Department has fulfilled its additional notice requirements.

3. The Notice of Hearing, the proposed rules and Statement of Need and Reasonableness (SONAR) complied with Minn. R. 1400.2080, subp. 5.

4. The Department has fulfilled the procedural requirements of Minn. Stat. § 14.14 and all other procedural requirements of law or rule.

5. The Department has demonstrated its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1; 14.15, subd. 3; and 14.50 (i) and (ii).

6. The Department has demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14 and 14.50.

7. The modification to the proposed rules suggested by the Administrative Law Judge after publication of the proposed rules in the *State Register* are not substantially different from the proposed rules as published in the *State Register* within the meaning of Minn. Stat. §§ 14.05, subd. 2, and 14.15, subd. 3.

8. As part of the public comment process, a number of stakeholders urged the Department to adopt other revisions to Part 4604. In each instance, the Agency's rationale in declining to make the requested revisions to its rules was well grounded in this record and reasonable.

9. A Finding or Conclusion of need and reasonableness with regard to any particular rule subsection does not preclude and should not discourage the Department from further modification of the proposed rules based upon this Report and an examination of the public comments, provided that the rule finally adopted is based upon facts appearing in this rule hearing record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS HEREBY RECOMMENDED that the proposed amended rules be adopted.

Dated: August 28, 2013

s/Eric L. Lipman
ERIC L. LIPMAN
Administrative Law Judge

Reported: 1 Transcript.

NOTICE

This Report must be available for review to all affected individuals upon request for at least five working days before the agency takes any further action on the rules. The agency may then adopt the final rules or modify or withdraw its proposed rule. If the agency makes any changes in the rule, it must submit the rule to the Chief Administrative Law Judge for a review of the changes prior to final adoption. Upon adoption of a final rule, the agency must submit a copy of the Order Adopting Rules to the Chief Administrative Law Judge. After the rule's adoption, the OAH will file certified copies of the rules with the Secretary of State. At that time, the agency must give notice to all persons who requested to be informed when the rule is adopted and filed with the Secretary of State.