

03-042  
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**Carol Roessler**  
STATE SENATOR

To: Members of the Senate Committee on Health, Children, Families, Aging and Long Term Care

From: Senator Carol Roessler, Chair

Date: July 9, 2003

Re: Clearinghouse Rule 03-042, relating to critical access hospitals  
Annual Statewide Immunization Program Report

CR 03-042 has been referred to the Senate Health, Children, Families, Aging and Long Term Care Committee. Through this proposed rule the Department of Health and Family Services (DHFS) is modifying provisions in subchapter VI of chapter HFS 124 to permit St. Mary's Hospital in Superior to be classified as a rural hospital and begin the approval process for designation as a Critical Access Hospital. In addition, DHFS is modifying several other provisions in subchapter VI of chapter HFS 124 to more closely reflect current federal regulations, the October 2001 Wisconsin Rural Hospital Flexibility Program Implementation Plan and to change the name of the federal Health Care Financing Administration to the Centers for Medicare and Medicaid Services.

If you would like the committee to hold a hearing on CR 03-042, please contact my office at 266-5300. The committee has jurisdiction over this rule until Friday, August 8, 2003.

In addition, as required by law, DHFS has issued the Annual Statewide Immunization Program Report. The report is enclosed for your review.

## AGENCY REPORT TO THE LEGISLATURE ON CLEARINGHOUSE RULE 03-042

### Need for Rules

The federal Rural Hospital Flexibility Program promotes the continued viability of rural hospitals by allowing qualifying hospitals to receive cost-based reimbursement for their services if the hospital qualifies for and is approved to convert to what is known as a Critical Access Hospital (CAH). In Wisconsin, subchapter VI of chapter HFS 124 governs the Department's designation and regulation of CAHs. Designation as a CAH and receipt of cost-based reimbursement promotes the hospital's continued viability. To date, 25 hospitals in Wisconsin have transitioned to CAH status, thereby ensuring continued acute care access for many rural residents.

The Department recently learned that the tenuous financial condition of St. Mary's Hospital in Superior jeopardizes its continued operation and places it in imminent danger of closing unless the hospital can be designated as a CAH and receive cost-based reimbursement. The closure of St. Mary's would reduce Douglas County residents' accessibility to acute care. Moreover, the loss of the facility would have a significant detrimental effect on the county because St. Mary's annual payroll is between \$7-8 million and it employs the equivalent of about 160 persons full-time.

Federal regulations permit a hospital in an urban area such as Superior to be reclassified as a critical access hospital if the hospital is located in an area designated as rural under state law or regulation. The Department has determined that the current provisions in chapter HFS 124 preclude St. Mary's from being reclassified as a rural hospital and designated as a necessary provider of health services to area residents. However, St. Mary's Hospital meets "necessary provider" status in the Wisconsin Rural Health Plan based on economic, demographic and health care delivery in its service area. Therefore, the Department is proposing to modify provisions in subchapter VI of chapter HFS 124 to permit St. Mary's Hospital to be classified as a rural hospital and begin the approval process for designation as a Critical Access Hospital. To permit St. Mary's to initiate its transition to a critical access hospital, the Department issued a similar emergency order that became effective on March 21, 2003. Through this proposed permanent order, the Department is also modifying several other provisions in subch. VI of ch. HFS 124 to more closely reflect current federal regulations, the October 2001 Wisconsin Rural Hospital Flexibility Program Implementation Plan and to change the name of the federal Health Care Financing Administration to the Centers for Medicare and Medicaid Services.

### Responses to Clearinghouse Recommendations

The Department accepted all of the Legislative Council's Rules Clearinghouse suggestions and comments.

### Final Regulatory Flexibility Analysis

The rule changes will not affect small businesses as defined in s. 227.114 (1) (a), Stats.

### Public Review

The Department held a combined public hearing on both the emergency and proposed permanent rulemaking order in Superior, Wisconsin at the Superior Public Library on June 20, 2003, beginning at 9:00 AM. The hearing officer was Janet Eakins, Section Chief, Provider Regulation and Quality Improvement Section, Bureau of Quality Assurance. The resource person was Jane Walters, Section Chief, Health and Social Services Section of the Bureau of Quality

Assurance. The hearing record remained open until June 23, 2003, for receipt of written comments. Participation in the hearing process is tabulated below. As indicated below, support for the rule was reflected by the positions indicated on the registrations or written statements filed by the hearing participants.

### CAH Hearing Participation

Provided oral testimony only at hearing:	7
Provided written comments only at hearing	1
Submitted written comments outside of hearing:	11
Supports rule:	17
Observer at hearing:	1

At the public hearing, seven people testified in support of St. Mary's Hospital in Superior achieving status as a Critical Access Hospital. The majority of comments were about how St. Mary's is a vital part of the local economy and the community as a whole. Everyone who submitted testimony indicated that it is imperative that St. Mary's gain Critical Access Hospital status to ensure the hospital's future in Superior and enhance the facility's vital health care provider role. Most of the patients served by St. Mary's are generally older and less financially stable. The elderly are very reluctant to drive to Duluth Hospital in Minnesota for health care. The economics are tough in Superior and the hospital provides many services to several people in the rural area that are underprivileged. The hearing attendees also supported both the emergency and proposed permanent rule because it provides the hospital an opportunity to increase revenue through cost-based reimbursement for Medicare and Medicaid patients, which gives the hospital greater service delivery flexibility.

The following is a complete list of the people who attended the public hearing or submitted written comments on the emergency and nearly identical proposed permanent rulemaking orders. With each person's name and affiliation is an indication of the person's position on the proposed rules and whether or not the person testified or provided written comments.

Name and Address	Position	Action
Roger P. Engle, President Superior Water Light & Power 2915 Hill Avenue P.O. Box 519 Superior, WI 54880	Supports	Submitted written comments; did not attend hearing
James Zastrow, President M&I-Marshall & Ilsley Bank 1425 Tower Avenue Superior, WI 54880-1029	Supports	Submitted written comments; did not attend hearing
Timothy L. Burke, MD Associate Medical Director St. Mary's/ Duluth Clinic System (SMDC) 3500 Tower Avenue Superior, WI 54880	Supports	Submitted written comments; did not attend hearing

Patrick D. Sura, MD St. Mary's/Duluth Clinic System (SMDC) 3500 Tower Avenue Superior, WI 54880	Supports	Submitted written comments; did not attend hearing
Dave Ross, Mayor Office of the Mayor 1407 Hammond Avenue Superior, WI 54880	Supports	Submitted written comments; did not attend hearing
Larry L. Kappes, President/CEO National Bank of Commerce 1127 Tower Avenue Superior, WI 54880	Supports	Submitted written comments; did not attend hearing
Jack Culley, CEO Sailboats Inc. 250 Marina Drive Superior, WI 54880	Supports	Submitted written comments; testified at hearing
Julius E. Erlenbach, Ph.D Chancellor-UW-Superior Old Main, Room 212 Belknap & Catlin, PO Box 2000 Superior, WI 54880-4500	Supports	Submitted written comments; did not attend hearing
Wende L. Nelson, Exec. Director Lake Superior Community Health Care 2 East 5 <sup>th</sup> Street Duluth, MN 55805-1711	Supports	Submitted written comments; did not attend hearing
Andrew Lisak, Exec. Director The Development Assoc., Inc. 1205 Tower Avenue Superior, WI 54880	Supports	Submitted written comments; testified at hearing
Janet H. Murphy, Board Member St Mary's Medical Ctr, St. Mary's Hospital Superior 3 Gitchinadji Drive Superior, WI 54880	Supports	Testified at hearing
Douglas G. Finn, Chair Douglas County Board of Supervisors 1313 Belknap Street Superior, WI 54880	Supports	Submitted written comments; testified at hearing
Naomi Stein 12195 E Danielson Road Maple, WI 54854	Supports Represents the Community	Testified at hearing

Kaye Tenerelli, Exec Director 809 E 8 <sup>th</sup> Street Superior, WI 54880	Supports	Submitted written comments; testified at hearing
Sherry L. Mattson 1627 N 34 <sup>th</sup> St Superior, WI 54880	Undecided	Hearing observer
Peter E. Person, MD, FACP, CEO St. Mary's/Duluth Clinic Health System 502 East Second Street Duluth, MN 55805	Supports	Submitted written comments; did not attend hearing
Stephen F. Brenton, President Wisconsin Hospital Assoc. 5721 Odana Road P.O. Box 44992 Madison, WI 53744-4992	Supports	Submitted written comments; did not attend hearing
Terry R. Jacobson, CEO 3500 Tower Avenue Superior, WI 54880	Supports	Submitted written comments; testified at hearing

PROPOSED ORDER OF THE  
DEPARTMENT OF HEALTH AND FAMILY SERVICES  
AMENDING AND CREATING RULES

The Department of Health and Family Services proposes an order to amend ss. HFS 124.38 (4), 124.39 (1) (intro), (a), (b) and (e), (2) (a) and (3), 124.40 (2) (b) and (3) and 124.41 and to create ss. HFS 124.38 (5) and 124.40 (2) (c), relating to critical access hospitals.

Analysis Prepared by the Department of health and Family Services

The federal Rural Hospital Flexibility Program promotes the continued viability of rural hospitals by allowing qualifying hospitals to receive cost-based reimbursement for their services if the hospital qualifies for and is approved to convert to what is known as a Critical Access Hospital (CAH). In Wisconsin, subchapter VI of chapter HFS 124 governs the Department's designation and regulation of CAHs. Designation as a CAH and receipt of cost-based reimbursement promotes the hospital's continued viability. To date, 25 hospitals in Wisconsin have transitioned to CAH status, thereby ensuring continued acute care access for many rural residents.

The Department recently learned that the tenuous financial condition of St. Mary's Hospital in Superior jeopardizes its continued operation and places it in imminent danger of closing unless the hospital can be designated as a CAH and receive cost-based reimbursement. The closure of St. Mary's would reduce Douglas County residents' accessibility to acute care. Moreover, the loss of the facility would have a significant detrimental effect on the county because St. Mary's annual payroll is between \$7-8 million and it employs the equivalent of about 160 persons full-time.

Federal regulations permit a hospital in an urban area such as Superior to be reclassified as a critical access hospital if the hospital is located in an area designated as rural under state law or regulation. The Department has determined that the current provisions in chapter HFS 124 preclude St. Mary's from being reclassified as a rural hospital and designated as a necessary provider of health services to area residents. However, St. Mary's Hospital meets "necessary provider" status in the Wisconsin Rural Health Plan based on economic, demographic and health care delivery in its service area. Therefore, the Department is proposing to modify provisions in subchapter VI of chapter HFS 124 to permit St. Mary's Hospital to be classified as a rural hospital and begin the approval process for designation as a Critical Access Hospital. To permit St. Mary's to initiate its transition to a critical access hospital, the Department issued a similar emergency order that became effective on March 21, 2003. Through this proposed permanent order, the Department is also modifying several other provisions in subch. VI of ch. HFS 124 to more closely reflect current federal regulations, the October 2001 Wisconsin Rural Hospital Flexibility Program Implementation Plan and to change the name of the federal Health Care Financing Administration to the Centers for Medicare and Medicaid Services.

The Department's authority to amend and create these rules is found under ss. 50.36 (1) and 227.11 (2) (a), Stats. The rules interpret s. 50.33 (1g) and (2) (c), Stats.

SECTION 1. HFS 124.38 (4) is amended to read:

HFS 124.38 (4) "Rural health plan" means a plan approved by the federal health care financing administration centers for medicare and medicaid services that describes how the department will implement and administer parts of the federal medicare rural hospital flexibility program---critical access hospitals---under 42 USC 1395i---4.

SECTION 2. HFS 124.38 (5) is created to read:

HFS 124.38 (5) "Rural hospital" means a hospital that was initially approved as a hospital prior to January 1, 2003 and is located in a county that has at least a portion of a rural census tract of a Metropolitan Statistical Area (MSA) as determined under the most recent version of the Goldsmith Modification as provided in 42 CFR 412.103(a)(1).

**Note:** The most recent version of the Goldsmith Modification as determined by the Office of Rural Health Policy (ORHP) of the Health Resources and Services Administration is available via the ORHP website at <http://ruralhealth.hrsa.gov/pub/Goldsmith.htm> or from the U.S. Department of Health and Human Services, Health Resources and Services Administration, Office of Rural Health Policy, 5600 Fishers Lane, Room 9A-55, Rockville, MD 20857. 42 CFR 412.103 of the federal regulations addresses hospitals located in urban areas that want to apply for reclassification as rural hospitals.

SECTION 3. HFS 124.39 (1) (intro), (a), (b) and (e) are amended to read:

HFS 124.39 Designation as a critical access hospital. (1) ELIGIBILITY. ~~To~~ Except as provided under sub. (2) (a), to be eligible for designation as a critical access hospital, a hospital shall be all of the following:

(a) ~~A nonprofit or public hospital approved by the department under this chapter to operate as a hospital.~~

(b) ~~Located in an area outside of a metropolitan statistical area as defined in 42 USC 1395ww(d), or located in a rural area of an urban county.~~

(e) ~~A hospital that has not been designated by the federal health care financing administration centers for medicare and medicaid services as an urban hospital for purposes of medicare reimbursement.~~

SECTION 4. HFS 124.39 (2) (a) and (3) are amended to read:

HFS 124.39 (2) APPLICATION FOR CERTIFICATION AS A NECESSARY PROVIDER FOR AN AREA. (a) 1. A hospital meeting the criteria under sub. (1) (a), (b), (d) and (e) may apply to the department for certification as a necessary provider of health care services to residents in its area if it cannot meet the criterion under sub. (1) (c) that it be located more than a 35-mile drive from another hospital.

2. A rural hospital meeting the criteria under sub. (1) (a), (d) and (e) may apply to the department for certification as a necessary provider of health care services to residents in its area if the rural hospital cannot meet the criteria under sub. (1) (b) and (c).

~~**Note:** To obtain the format for the application, write or phone: Bureau of Quality Assurance, P.O. Box 309, Madison, WI 53701-309; (608) 266-7297.~~

3. Application under subd. 1. or 2. shall be made in accordance with a format provided by the department.

**Note:** To obtain the format for the application, write or phone: Bureau of Quality Assurance, P.O. Box 2969, Madison, WI 53701-2969; (608) 266-7297.

(3) APPLICATION FOR CRITICAL ACCESS HOSPITAL STATUS. (a) A hospital eligible under sub. (1) or (2) (a) for designation as a critical access hospital may apply to the department for designation. Application shall be made in accordance with a format provided by the department.

**Note:** To obtain the format for the application, write or phone: Bureau of Quality Assurance, P.O. Box 3092969, Madison, WI 53701-3092969; (608) 266-7297.

(b) Upon receipt of a completed application from a hospital for designation as a critical access hospital, the department shall review the application and shall determine if the applicant meets the federal conditions of participation in medicare for critical access hospitals under 42 CFR 485.601 to 485.645, and, if applicable, 42 CFR 412.103(a)(1). If the applicant hospital meets those federal conditions of participation regulations and all requirements under ss. HFS 124.40 and 124.41, the department shall, within 90 days after receipt of a completed application, ~~certify~~ recommend certification of the hospital as a critical access hospital, ~~notify the hospital in writing of its action and submit its certification of the designation to the federal health care financing administration for acceptance centers for medicare and medicaid services.~~

**Note:** The federal Centers for Medicare and Medicaid Services will notify the Department and the applicant hospital of the certification decision.

(c) Following notification by the federal ~~health care financing administration~~ centers for medicare and medicaid services that it has accepted the department's certification recommendation, the department shall issue a certificate of approval that establishes the applicant's critical access hospital status in the state.

SECTION 5. HFS 124.40 (2) (b) is amended to read:

HFS 124.40 (2) (b) If the critical access hospital has an agreement established under 42 USC 1395tt governing the hospital's maintenance of swing beds, the critical access hospital may maintain ~~up to a total of not more than~~ 25 inpatient beds, of which no more than 15 beds may be used exclusively for acute inpatient care.

SECTION 6. HFS 124.40 (2) (c) is created to read:

HFS 124.40 (2) (c) A critical access hospital may have up to 4 additional permanently-placed 24-hour observation beds.

SECTION 7. HFS 124.40 (3) is amended to read:

HFS 124.40 (3) LIMITS ON ACUTE INPATIENT STAYS. A critical access hospital shall provide inpatient care for periods not to exceed an annual average of 96 hours, unless a per patient. The hospital shall record each patient's stay and any longer inpatient stay is required because transfer to a network or other hospital is precluded due to inclement weather or other emergency conditions.

SECTION 8. HFS 124.41 is amended to read:

HFS 124.41 Rural health plan. Before implementation of the state medicare rural hospital flexibility program pursuant to 42 USC 1395i-4 for the establishment of critical access hospitals, the department shall develop a rural health plan. The department shall submit the rural health plan to



the federal health care financing administration centers for medicare and medicaid services for approval.

The rules contained in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, as provided in s. 227.22 (2), Stats.

Wisconsin Department of Health  
and Family Services

Dated:

By: \_\_\_\_\_  
Helene Nelson  
Secretary

SEAL:

**Fiscal Estimate – 2001 Session**

<input checked="" type="checkbox"/> Original	<input type="checkbox"/> Updated	LRB Number	Amendment Number if Applicable
<input type="checkbox"/> Corrected	<input type="checkbox"/> Supplemental	Bill Number	Administrative Rule Number HFS 124

Subject  
 Designation as a Critical Access Hospital

**Fiscal Effect**

State:  No State Fiscal Effect  
 Check columns below only if bill makes a direct appropriation or effects a sum sufficient appropriation.

<input checked="" type="checkbox"/> Increase Existing Appropriation	<input type="checkbox"/> Increase Existing Revenues	<input checked="" type="checkbox"/> Increase Costs – May be possible to absorb within agency's budget. <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/> Decrease Existing Appropriation	<input type="checkbox"/> Decrease Existing Revenues	
<input type="checkbox"/> Create New Appropriation	<input type="checkbox"/> Decrease Costs	

Local:  No Local Government Costs

1. <input type="checkbox"/> Increase Costs <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	3. <input type="checkbox"/> Increase Costs <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	5. Types of Local Government Units Affected: <input type="checkbox"/> Towns <input type="checkbox"/> Villages <input type="checkbox"/> Cities <input type="checkbox"/> Counties <input type="checkbox"/> Others: <input type="checkbox"/> School Districts <input type="checkbox"/> WCTS Districts
2. <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	4. <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	

Fund Sources Affected <input checked="" type="checkbox"/> GPR <input checked="" type="checkbox"/> FED <input type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S	Affected Chapter 20 Appropriations 20.435 (4) (b), 20.435 (4) (o)
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**Assumptions Used in Arriving at Fiscal Estimate**  
 A hospital may be designated as a critical access hospital if it satisfies federal and state requirements including requirements specified under HFS 124.37 through 124.41.

Section HFS 124.39 (1) of the Wisconsin Administrative Code specifies state eligibility requirements for designation as a critical access hospital. A hospital must meet all of the following:

- (a) A nonprofit or public hospital approved by the department to operate as a hospital.
- (b) Located in an area outside of a metropolitan statistical area as defined in 42 USC 1395ww(d).
- (c) Located more than a 35-mile drive from another hospital or certified by the department under sub. (2) as a necessary provider of health care services to residents in the area.
- (d) A hospital that has a provider agreement to participate in Medicare in accordance with 42 CFR 485.612.
- (e) A hospital that has not been designated by the federal health care financing administration as an urban hospital for the purposes of Medicare reimbursement.

A hospital that satisfies all criteria under HFS 124.39 (1) except that it is located more than 35 miles from another hospital can be designated under HFS 124.39 (2) as a necessary provider and meet all criteria under HFS 124.39 (1). Designation as a necessary provider under HFS 124.39 (2) is contingent on meeting criteria HFS 124.39 (1) (a), (b), (d), and (e).

The proposed rule change would expand the criteria for necessary providers under HFS 124.39 (2) to rural hospitals, defined as hospitals located in a county that has at least a portion of a rural census tract of a metropolitan statistical area as determined under the most recent version of the Goldsmith Modification as provided in 42 CFR 412.103(a)(1), that meet the criteria under HFS 123.39 (1) (a), (d) and (e).


Two counties in Wisconsin currently fall under Goldsmith Modification criteria: Douglas and Marathon. Three hospitals are located in these counties: St. Mary's in Superior, and NorthCentral Health Care Facility and Wausau Hospital in Wausau. None of these hospitals currently meet the requirements for a critical access hospital under HFS 124.40. However, St. Mary's has expressed an interest in delicensing a number of its hospital beds. If St. Mary's were to delicense 137 beds, it would meet the requirements under 124.40 and could gain critical access hospital status under the proposed change.

If St. Mary's were to gain critical access hospital status, it would be eligible for inpatient and outpatient hospital cost-based reimbursement under fee-for-service Medicaid (MA), as well as increased federal Medicare payments. Under cost-based reimbursement, it is estimated St. Mary's would receive an MA increase of \$285,200 AF (\$118,400 GPR) annually. This increase includes the effect of eliminating Metropolitan Border Status Supplement payments. St. Mary's currently receives \$152,500 AF in MA payments under the Metropolitan Border Status Supplement. Under cost-based reimbursement, St. Mary's would not be eligible for supplemental MA payments.

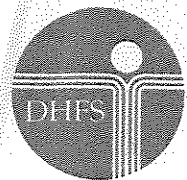
In addition, the Department would lose approximately \$2,500 PR annually in bed licensing fees from St. Mary's due to the 137 delicensed beds.

Due to estimated increased MA payments and loss of bed licensing fees, this change has a state fiscal estimate of \$287,700 AF (\$118,400 GPR). This change has no fiscal effect for local governments.

Long Range Fiscal Implications

Prepared By: Anne Miller	Telephone Number 608-266-5422	Agency DHFS
Authorized Signature 	Telephone Number 608 266 9622	Date (mm/dd/ccyy) 03/17/03

DHFS / EXS-9001 (9/02)



State of Wisconsin  
**Department of Health and Family Services**

*Health*

Jim Doyle, Governor  
Helene Nelson, Secretary

July 7, 2003

Donald J. Schneider  
Senate Chief Clerk  
17 West Main, Suite 401  
Madison, WI 53707

Dear Mr. Schneider:

As required by s. 252.04(11), Wis. Stats., enclosed is the Annual Statewide Immunization Program Report. Please distribute this report to the appropriate standing committees.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Helene Nelson'.

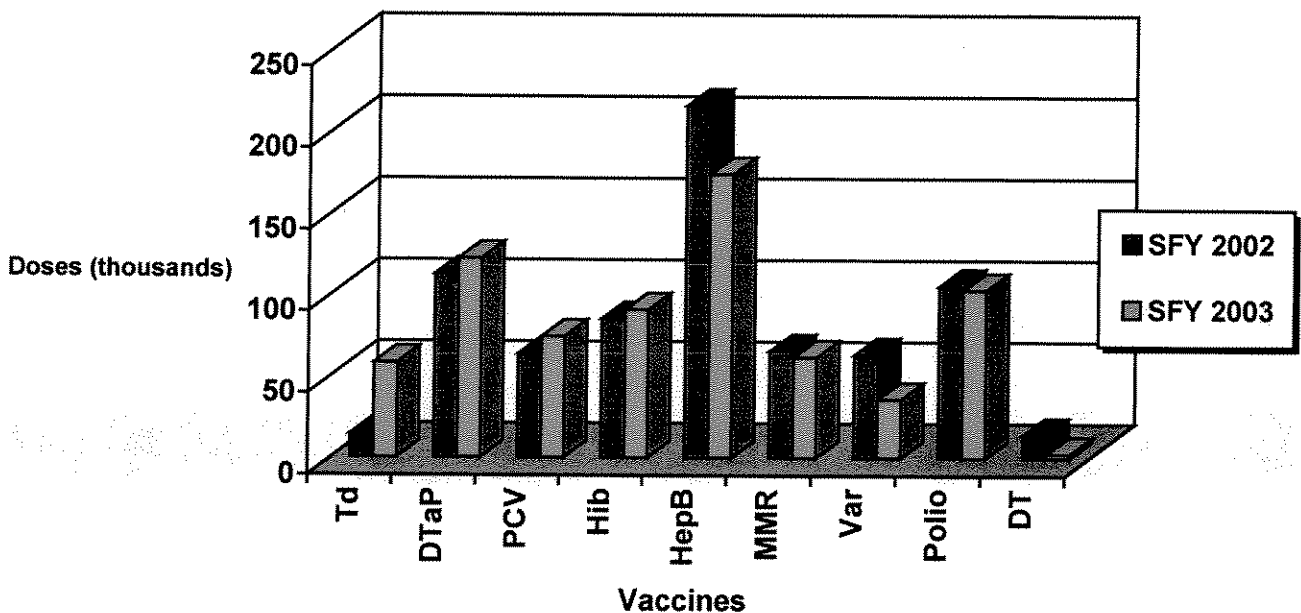
Helene Nelson  
Secretary

Immunization Program Annual Report  
State Fiscal Year 2003

A. Vaccine Distribution

The graph below demonstrates the total doses of vaccine by type distributed to Wisconsin health care providers during the state fiscal years (SFY) 2002 and 2003. Those providers include public health departments, community health centers, tribal health clinics, juvenile detention centers, selected schools and private providers enrolled in the Vaccines For Children program. For the sake of comparability in this report, the state fiscal year data represents the time period of May 28<sup>th</sup> of one year to May 28<sup>th</sup> of the next.

**Vaccines Distributed By the Wisconsin Immunization Program  
SFY 2002 and 2003**



**Definitions:**

- Td means combined Tetanus and Diphtheria (ages 7 years and older)
- DTaP means combined Diphtheria, Tetanus and acellular Pertussis
- PCV means Pneumococcal Conjugate Vaccine
- Hib means *Haemophilus influenzae* type B
- Hep B means Hepatitis B
- MMR means combined Measles, Mumps and Rubella
- Var means Varicella (chickenpox)
- Polio includes inactivated and/or oral vaccines
- DT means combined Diphtheria and Tetanus (ages 2 months to 7 years)

In SFY 2003 the majority of vaccine distributed by the Wisconsin Immunization Program did not change appreciably from SFY 2002. Those vaccines showing a significant change include a three-fold increase in Td and a decline in hepatitis B and varicella by 19% and 43% respectively.

In April 2001, we mailed a memo to all users of state supplied vaccine announcing the national shortage of Td vaccine. This shortage was caused by one of the two US Td manufacturers no longer producing the product. In June 2002, we announced to the same users of state supplied vaccine that the shortage had abated and supplies of the vaccine were at near normal levels and that routine vaccination could resume. This accounts for the increase in Td distribution in Wisconsin.

Hepatitis B vaccine was first required for kindergarten and 7<sup>th</sup> grade students in the 1997-98 school year and will be phased in to grades K-12 by the 2003-2004 school year. Most public health departments offered the vaccine to all children including those for whom it was not required. As a result, many students voluntarily received the vaccine before they were required to receive it. This may explain the continuing decline in distribution of Hepatitis B vaccine in subsequent years.

The decrease in varicella vaccine distribution may be due to the completion of varicella vaccination in most children attending day care during 2001, the year the vaccine requirement was implemented. An increase in demand for varicella vaccine is expected when the phase-in requirement accelerates from grades K through 2nd (and day care centers) during the 2003-04 school year to grades K through 8<sup>th</sup> (and day care centers) in the 2004-2005 school year.

Of note is the consistent level of pneumococcal conjugate vaccine (PCV) distribution, which, under normal circumstances, should be higher. In January 2002, a memo was mailed to all users of state supplied vaccines announcing manufacturing delays and an indefinite delay in the distribution of the vaccine. The routine dose schedule for infants was reduced from 4 doses to 2 doses in order to conserve vaccine and provide preliminary protection to the largest number of children. In May 2003, we announced that the delay in vaccine supply was over and providers can go back to the recommended 4 dose regimen. Doses distributed should increase during the next state fiscal year.

All of these shortages have frustrated parents and health care providers and point out the fragile nature of the US vaccine supply that is influenced by new FDA requirements and corporate vaccine manufacturers decisions.

#### B. Disease Surveillance (Calendar Year 2002)

1. There were no cases of rubella, polio, diphtheria and tetanus reported in Wisconsin.
2. There was one case each of mumps and measles reported. The measles case was imported from India.
3. There were 50 cases of acute hepatitis B reported.
4. There were 180 pertussis cases reported. Twenty eight percent of those cases

were from an outbreak centered in high school and middle school aged students in the Madison area. This was a frustrating outbreak since pertussis vaccine is only licensed for person less than 7 years of age. Older cases and their contacts were investigated and offered antibiotic treatment. Of the total statewide cases reported 74 were in persons above 7 years of age.

5. There were 1,116 cases of Varicella (chickenpox) reported. Chickenpox is the only vaccine preventable disease that is reportable by aggregate number rather than name and age. This is a holdover from the time before varicella vaccine was available. The Council of State and Territorial Epidemiologists recommend that by 2005 varicella be reported by name and age, like other vaccine preventable diseases.

C. Assessments

1. Schools (grades K-12): The table entitled "Wisconsin Student Immunization Law Compliance Results" (attachment 1), demonstrates compliance with the law among all public and non-public school students in kindergarten through twelfth grade, from the time period 1989 through 2003. In general, the levels of compliance and non-compliance have not changed appreciably. However, the percent of children whose parents claim a waiver for personal conviction reasons has risen slowly over the past 14 years.
2. Schools (Kindergarten): Kindergarten immunization levels are assessed each year through an on site sampling of randomly selected elementary schools in Wisconsin. Immunization Program personnel collect and summarize data from the Student Immunization Records of kindergarten children. The results for the past 2 years are listed in the table below.

**Kindergarten Immunization Assessment  
School year 2001-2002 and 2002-2003**

	2001-2002	2002-2003
<b>No immunization records</b>	<b>0.9</b>	<b>1.5</b>
<b>Waivers (any type)</b>	<b>3.2</b>	<b>4.9</b>
<b>DTaP (4+ doses)</b>	<b>87.4</b>	<b>96.2</b>
<b>Polio (3+doses)</b>	<b>96.2</b>	<b>95.9</b>
<b>MMR (2 dose)</b>	<b>83.8</b>	<b>89.6</b>
<b>Hep B (3 + doses)</b>	<b>92.4</b>	<b>94.7</b>
<b>Varicella</b>	<b>84.9</b>	<b>76.7</b>
<b>Series Complete*</b>	<b>74.8</b>	<b>84.9</b>

\* Series complete = 4:3:2:3: (4 DTaP: 3 Polio:2 MMR: 3 Hep B), varicella not included

3. Day Care and Head Start: The immunization coverage levels from all licensed day care centers, including Head Starts, are determined annually by a mail-in survey to the Wisconsin Immunization Program. There are over 5,000 licensed day care centers in Wisconsin. Many local health departments provide immunization information and services to the centers and through their efforts, as part of consolidated contract funding, the rate of return for the 2002 survey increased by 19% over the previous year. The survey results among children 2 years through 4 years of age for 2001 and 2002 are listed below.

**Day Care Immunization Assessment  
CY 2001 and 2002**

	Day Care Center		Head Start	
	2001	2002	2001	2002
<b>No immunization records</b>	2.6%	3.2%	2.7%	4.5%
<b>Waivers (any type)</b>	3.2%	2.7%	1.4%	1.1%
<b>DTaP (4+ doses)</b>	90.8%	89.8%	89.3%	90.7%
<b>Polio (3+doses)</b>	92.6%	91.6%	92.3%	91.9%
<b>MMR (1 dose)</b>	93.2%	94.5%	93.8%	93.7%
<b>Hib (3+ doses)</b>	93.6%	91.3%	92.1%	92.1%
<b>Hep B (3 + doses)</b>	92.6%	91.0%	91.3%	92.0%
<b>Varicella Vaccine</b>	61.9%	79.5%	66.9%	80.0%
<b>Varicella disease history</b>	9.0%	7.2%	6.7%	7.7%
<b>Series Complete*</b>	67.7%	80.4%	60.9%	79.0%

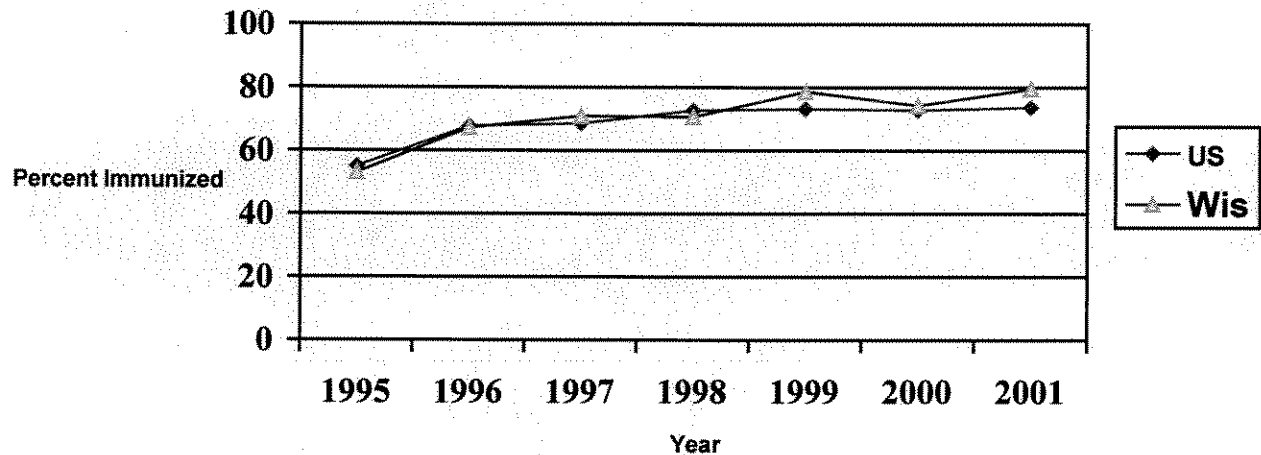
\* Series complete = 4:3:1:3:3:1 (4 DTaP: 3 Polio:1 MMR: 3 Hib, 3 Hep B: 1 Var)

4. Preschool: Estimates of immunization levels of preschool children 2 years of age are determined by the National Immunization Survey (NIS) that is funded by the Centers for Disease Control and Prevention. The NIS is an ongoing, random-digit telephone sample survey that estimates immunization levels of children two years of age (defined as age 19 months through 35 months) throughout the United States. A new cohort of children 2 years of age is surveyed each year. Immunization dates are obtained from parents and later verified with their health care provider. These data can vary from year to year due to the 95% confidence intervals but the overall trend demonstrates an increase over time. The line graph below compares the percentage of children 2 years of age who are series complete in Wisconsin vs. the US for past seven years.



**Estimated Series Complete\* Vaccine Coverage  
Among Children Two Years of Age  
Wisconsin and US  
CY1995-2001**

**Source: National Immunization Survey**



\* 4 DTaP, 3 Polio, 1 MMR, 3 Hib and 3 Hep B

**D. Wisconsin Immunization Registry**

The Wisconsin Immunization Program has developed and implemented the Wisconsin Immunization Registry (WIR). The WIR is a web based computerized database that assists public and private health care providers in keeping children on schedule for recommended immunizations. The State of Wisconsin offers the WIR at no cost to providers. Providers need only a personal computer with Internet access. A help desk is available to all users. Security systems are in place to prevent unauthorized access or manipulation of the information. Prior to use of the WIR, the organization and user must sign the Security and Confidentiality Agreement. All WIR data is encrypted and password protected. Parents have the option to "opt out" before birth data is entered as well as at any time a provider administers a vaccine.

The registry:

1. centralizes record keeping for health care providers;
2. assists providers in determining which immunizations are needed and when, even if

the child receives immunizations from multiple providers;

3. issues reminders to parents when immunizations are due and recall notices if a child falls behind schedule;
4. provides parents access to their child's immunization records through the Internet;
5. monitors vaccine inventory; and
6. monitors immunization levels and trends in the population.

Currently, 500 provider organizations at 1,500 sites representing 7,237 users are on the WIR. There are over 2.5 million client records and over 17.3 million associated immunizations. Each day, 5,000 new vaccine administration dates or historical dates are added to the WIR. In addition, 1,000 users access the WIR at any given time throughout the day. Over 1,500 schools have "look up only" access to the WIR.

The WIR user can obtain reports on children needing vaccines and doses of vaccines administered. A statewide report of the number of clients on the WIR (attachment 2) has been produced. Using Geographic Information Systems (GIS) demo software, a map was produced showing the distribution of children who have received at least 1 dose of vaccine from the Dane County health department (Attachment 3). This map clearly demonstrates the mobility of families with children and the need for a registry to share immunization data with other providers.

Future WIR enhancements include the addition of the GIS for use by providers. By analyzing immunization levels in geographic areas such as ZIP CODE, census tract or school district, pockets of need can be identified and resources targeted to raise immunization coverage levels. Other enhancements will include the development of a real time interface with electronic medical record systems, automatic ordering of state supplied vaccines based on inventory threshold levels and electronic signatures for a paperless system.

Wisconsin Student Immunization Law Compliance Results<sup>1</sup>  
Public and Private Schools  
Kindergarten (and Pre-K) through 12th Grade  
School Year

	89-90	90-91 <sup>4</sup>	91-92	92-93	93-94	94-95	95-96	96-97	97-98 <sup>5</sup>	98-99	99-00	00-01	01-02 <sup>6</sup>	02-03
Meet Minimum.	95.9%	94.6%	95.0%	94.6%	94.7%	94.6%	94.7%	96.3%	92.2%	92.4%	92.5%	92.4%	92.0%	91.5%
In Process <sup>2</sup>	0.5%	1.9%	1.5%	1.8%	1.6%	1.6%	1.7%	0.8%	4.1%	2.4%	1.9%	1.7%	1.5%	1.5%
Medical Waiver	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.4%
Religious Waiver	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Personal Convict. Waiver	0.7%	0.7%	0.8%	0.8%	0.9%	0.9%	1.0%	1.0%	1.2%	1.4%	1.7%	1.9%	2.3%	2.6%
Behind Schedule <sup>3</sup>	1.5%	1.5%	1.4%	1.5%	1.5%	1.6%	1.4%	0.8%	1.3%	2.6%	2.7%	2.7%	2.8%	2.8%
No Record	1.0%	0.9%	0.6%	0.7%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.7%	0.6%	0.6%	0.7%

<sup>1</sup> Compliant students include the rows labeled "Meet Minimum", "In Process", "Medical Waiver", "Religious Waiver" and "Personal Conviction Waiver".  
<sup>2</sup> "In Process" means the student received the first dose of required vaccines within 30 school days, the second dose within 90 school days, and the third dose (and fourth dose if required) within 30 school days the following school year.  
<sup>3</sup> "Behind Schedule" means the student missed the deadline for the first, second, or final doses of vaccine.  
<sup>4</sup> Second doses of MMR vaccine added as a requirement for kindergartners, 6th and 12th graders.  
<sup>5</sup> Hepatitis B vaccine added as a requirement for kindergartners and 7th grade.  
<sup>6</sup> Varicella vaccine added as a requirement for kindergarten.

# Children on WIR

Birth Year	# of Clients	# of clients w/Imms	# of Immunizations	% with Immunizations	Average # of Imms
1990	70,142	70,055	715,921	100%	10
1991	64,532	64,453	745,267	100%	12
1992	59,231	59,140	733,141	100%	12
1993	58,194	58,113	707,666	100%	12
1994	58,578	58,469	696,442	100%	12
1995	77,864	57,928	694,655	74%	12
1996	77,395	59,200	755,903	76%	13
1997	76,154	58,507	796,313	77%	14
1998	76,007	56,870	750,251	75%	13
1999	76,383	58,268	770,405	76%	13
2000	73,585	59,783	829,056	81%	14
2001	70,213	56,612	750,625	81%	13
2002	69,625	45,807	420,861	66%	9
2003	17,313	4,723	14,336	27%	3

Clients with at least 1  
immunization from Dane  
County Health Department

