

PERFORMANCE AUDIT
OF THE
BUREAU OF HEALTH SYSTEMS
DEPARTMENT OF COMMUNITY HEALTH

January 2005

“...The auditor general shall conduct post audits of financial transactions and accounts of the state and of all branches, departments, offices, boards, commissions, agencies, authorities and institutions of the state established by this constitution or by law, and performance post audits thereof.”

– Article IV, Section 53 of the Michigan Constitution

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Michigan
Office of the Auditor General
REPORT SUMMARY

Performance Audit

Report Number:
 63-450-03

Bureau of Health Systems

Released:
 January 2005

Department of Community Health

The Bureau of Health Systems' (BHS's) stated mission is to protect and improve the health status of Michigan's population through the development, maintenance, and assurance of safe, effective, efficient, and accessible health care services delivered through health care facilities, organizations, systems, and personnel and to promote the development of appropriate regulatory policies to achieve a safe, effective, and efficient health care delivery system.

Audit Objectives:

1. To assess the effectiveness of BHS's Division of Licensing and Certification and Division of Health Facilities and Services' Emergency Medical Services Section and Radiation Safety Section in performing their licensing, registering, and monitoring functions.
2. To assess BHS's effectiveness and efficiency in processing consumer complaints.

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Audit Conclusions:

1. The Division of Licensing and Certification was generally effective in performing its licensing and monitoring functions of hospitals and psychiatric hospitals, programs, and units. However, the Division of Licensing and Certification was only marginally effective in performing its licensing and monitoring functions of other health care facilities, including hospices, freestanding surgical outpatient facilities, substance abuse treatment programs, and hospice

residences. We also concluded that the Emergency Medical Services Section and Radiation Safety Section were generally effective in performing their licensing, registering, and monitoring functions of medical first responders, life support agencies and life support vehicles, and x-ray machines and facilities.

2. BHS was generally effective and efficient in processing consumer complaints. Our report does not include any reportable conditions related to this audit objective.

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Noteworthy Accomplishments:

In October 2001, BHS entered into a joint project with the Renal Network of the Upper Midwest, Inc., with the overall goal to improve the end stage renal disease patient care system. This collaborative effort was the result of recommendations made by the federal Office of the Inspector General in its external quality review of dialysis facilities.

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Material Condition:

BHS did not sufficiently survey or inspect hospices, freestanding surgical outpatient facilities, substance abuse treatment programs, and hospice residences. Also, BHS had not established formal policies and procedures to effectively prioritize and schedule required surveys and inspections of licensed health care facilities. (Finding 1)

Other Conditions:

BHS's Care*Net data system and substance abuse computer information data system contained inaccurate information (Finding 2).

BHS had not assessed all clinical laboratories to determine if they fall under State licensing requirements. Consequently, BHS had not licensed any clinical laboratories, as required by State law. BHS had not licensed clinical laboratories because it relies on federal certification of these facilities. However, BHS had not obtained amendatory legislation to modify State licensure requirements to allow for reliance on federal clinical laboratory certification procedures, if such certification fulfills State licensing requirements. (Finding 3)

BHS had not established a process to assess the need for and quality of emergency medical services throughout the State, as required by State law (Finding 4).

BHS needs to improve its controls to ensure that radiation machines are properly registered and monitored as required by the *Michigan Administrative Code* (Finding 5).

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Agency Response:

Our audit report contains 5 findings and 7 corresponding recommendations. BHS's preliminary response indicated that it agrees with all of our findings and recommendations.

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Background:

Throughout the period covered by this audit, BHS was located within the Department of Consumer and Industry Services. However, the Governor, through Executive Order No. 2003-18, transferred BHS to the Department of Community Health, effective December 7, 2003.

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A copy of the full report can be obtained by calling 517.334.8050 or by visiting our Web site at: <http://audgen.michigan.gov>



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AUDITOR GENERAL

January 7, 2005

Ms. Janet Olszewski, Director
Department of Community Health
Lewis Cass Building
Lansing, Michigan

Dear Ms. Olszewski:

This is our report on the performance audit of the Bureau of Health Systems, Department of Community Health.

This report contains our report summary; description of agency; audit objectives, scope, and methodology and agency responses and prior audit follow-up; comments, findings, recommendations, and agency preliminary responses; a summary schedule of licensed and certified facilities by type, presented as supplemental information; and a glossary of acronyms and terms.

Our comments, findings, and recommendations are organized by audit objective. The agency preliminary responses were taken from the agency's response subsequent to our audit fieldwork. The *Michigan Compiled Laws* and administrative procedures require that the audited agency develop a formal response within 60 days after release of the audit report.

We appreciate the courtesy and cooperation extended to us during this audit.

AUDITOR GENERAL

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Description of Agency

The Bureau of Health Systems' (BHS's) stated mission* is to protect and improve the health status of Michigan's population through the development, maintenance, and assurance of safe, effective, efficient, and accessible health care services delivered through health care facilities, organizations, systems, and personnel and to promote the development of appropriate regulatory policies to achieve a safe, effective, and efficient health care delivery system. BHS attempts to achieve its mission by issuing licenses, performing surveys and inspections, and investigating complaints of health care facilities and organizations.

Throughout the period covered by this audit, BHS was located within the Department of Consumer and Industry Services. However, the Governor, through Executive Order No. 2003-18, transferred BHS to the Department of Community Health, effective December 7, 2003.

BHS is composed of four divisions:

1. The Division of Licensing and Certification seeks to protect the health and safety of individuals receiving care in health care facilities (other than long-term health care facilities) through the performance of facility surveys and inspections. The objectives of the surveys and inspections are to verify compliance with licensure and certification standards, to provide technical assistance to facilities in meeting those standards, to pursue appropriate corrective action of facility deficiencies, and to license and recommend certification of facilities for Medicare and Medicaid reimbursement. The authority for performing these functions is provided by Sections 333.20101 - 333.22260 of the *Michigan Compiled Laws*.

The Division is responsible for licensing, surveying, and monitoring approximately 3,000 health care facilities. The types of facilities monitored include ambulatory surgical centers; clinical laboratories; comprehensive outpatient rehabilitation facilities; end stage renal disease facilities; freestanding surgical outpatient facilities; home health agencies; hospices; hospice residences; hospitals;

* See glossary at end of report for definition.

outpatient physical therapy facilities; portable x-ray facilities; psychiatric hospitals, partial hospitalization psychiatric programs, and psychiatric units in general hospitals; rural health clinics; and substance abuse programs.

2. The Division of Operations is responsible for the receipt and investigation of nursing home residents' complaints and facility-reported incidents involving serious injury or harm; for referral of non-long-term care complaints for investigation; for development, processing, and coordination of enforcement actions undertaken by BHS in the performance of its regulatory functions; for data management; and for staff training.
3. The Division of Health Facilities and Services is divided into three sections:
 - a. The Health Facilities Evaluation Section conducts physical plant evaluations, including plan review and issuance of construction permits for new construction and modernization projects for health care facilities. The Section also conducts licensing and certification surveys of licensed health care facilities to identify and resolve operational, environmental, and infection control problems and conducts the physical plant and infection control portions of complaint investigations at hospitals.

The Section reported that it annually reviews approximately 600 sets of architectural/engineering plans, issues 200 construction permits, and conducts 300 opening surveys of health care facilities.

- b. The Emergency Medical Services Section is responsible for annually licensing approximately 800 medical first responder and life support agencies and approximately 2,700 life support vehicles in accordance with Sections 333.20901 - 333.20979 of the *Michigan Compiled Laws*. Also, the Section approves local medical control authorities, i.e., the hospitals or groups of hospitals that provide community-based prehospital emergency care oversight. Each county or group of counties is required to have a medical control authority, which has the responsibility to establish policies, procedures, and protocols detailing how prehospital care will be carried out within the geographic area. The Section approves each of the 65 medical control authorities' prehospital care policies, procedures, and protocols prior to implementation.

- c. The Radiation Safety Section is responsible for annually registering approximately 26,000 x-ray machines used in about 9,800 medical and nonmedical radiation facilities in accordance with Sections 333.13501 - 333.13536 of the *Michigan Compiled Laws*. The Section conducts periodic radiation safety inspections at all registered facilities to ensure protection of patients, employees, and the public from unnecessary radiation exposure. Also, the Section grants legal authorization for specialized x-ray machines used for mammography and conducts annual inspections of approximately 330 mammography facilities for compliance with federal and State mammography quality assurance requirements.
4. The Division of Nursing Home Monitoring is responsible for the survey, investigation, assessment, and evaluation of long-term health care facilities to verify compliance with Medicare/Medicaid certification and State licensure requirements. The emphasis of these activities is to protect the health and safety of vulnerable individuals and to improve the quality of life and quality of care for nursing home residents. This Division was excluded from this audit because it was recently reviewed in our performance audit of the Regulation of Nursing Homes, Adult Foster Care Homes, and Homes for the Aged, Department of Consumer and Industry Services (#6345199), released in April 2001.

Audit Objectives, Scope, and Methodology and Agency Responses and Prior Audit Follow-Up

Audit Objectives

Our performance audit* of the Bureau of Health Systems (BHS), Department of Community Health, had the following objectives:

1. To assess the effectiveness* of BHS's Division of Licensing and Certification and Division of Health Facilities and Services' Emergency Medical Services Section and Radiation Safety Section in performing their licensing, registering, and monitoring functions.

2. To assess BHS's effectiveness and efficiency* in processing consumer complaints.

Audit Scope

Our audit scope was to examine the program and other records of the Bureau of Health Systems. Our audit was conducted in accordance with *Government Auditing Standards* issued by the Comptroller General of the United States and, accordingly, included such tests of the records and such other auditing procedures we considered necessary in the circumstances.

Audit Methodology

Our audit procedures, conducted from July through November 2003, included examination of BHS's records and activities primarily for the period October 1, 2001 through October 31, 2003.

We conducted a preliminary review of BHS's operations to formulate a basis for defining the audit objectives and scope. Our preliminary review included interviewing BHS personnel, reviewing applicable statutes and regulations, analyzing available data and statistics, and reviewing BHS policies and procedures to obtain an understanding of BHS's operational activities.

To accomplish our first objective, we obtained an understanding of the regulations, policies, and procedures used by BHS to regulate the health care facilities that it

* See glossary at end of report for definition.

monitors. We reviewed BHS's procedures for licensing facilities and performing annual or biennial facility surveys and inspections. We selected a sample of facility files to evaluate the licensing and survey process. We verified the Emergency Medical Services Section's approval of each county's or group of counties' medical control authority and prehospital care procedures. In addition, we reviewed the Section's procedures for licensing and inspecting life support agencies and life support vehicles. Finally, we assessed the Radiation Safety Section's procedures for registering and inspecting x-ray machines and medical and nonmedical radiation facilities.

To accomplish our second objective, we obtained an understanding of the policies and procedures related to processing consumer complaints against health care facilities monitored by BHS. We selected a sample of complaints to verify that they were properly recorded and processed on a timely basis.

Agency Responses and Prior Audit Follow-Up

Our audit report contains 5 findings and 7 corresponding recommendations. BHS's preliminary response indicated that it agrees with all of our findings and recommendations.

The agency preliminary response that follows each recommendation in our report was taken from the agency's written comments and oral discussion subsequent to our audit fieldwork. Section 18.1462 of the *Michigan Compiled Laws* and Department of Management and Budget Administrative Guide procedure 1280.02 require the Department of Community Health to develop a formal response to our audit findings and recommendations within 60 days after release of the audit report.

Our prior audit of the Bureau of Health Systems was released in December 1993 (#3512093). At that time, BHS was a part of the Department of Public Health. We followed up 3 of the 16 prior audit recommendations within the scope of this audit. BHS complied with 1 of the prior audit recommendations; the other 2 were rewritten for inclusion in this report.

COMMENTS, FINDINGS, RECOMMENDATIONS,
AND AGENCY PRELIMINARY RESPONSES

EFFECTIVENESS IN PERFORMING LICENSING, REGISTERING, AND MONITORING FUNCTIONS

COMMENT

Audit Objective: To assess the effectiveness of the Bureau of Health System's (BHS's) Division of Licensing and Certification and Division of Health Facilities and Services' Emergency Medical Services Section and Radiation Safety Section in performing their licensing, registering, and monitoring functions.

Conclusion: We concluded that the Division of Licensing and Certification was generally effective in performing its licensing and monitoring functions of hospitals and psychiatric hospitals, programs, and units. However, the Division of Licensing and Certification was only marginally effective in performing its licensing and monitoring functions of other health care facilities, including hospices, freestanding surgical outpatient facilities (FSOFs), substance abuse treatment programs, and hospice residences. Our assessment disclosed a material condition* related to the monitoring of these other licensed health care facilities (Finding 1). We also concluded that the Emergency Medical Services Section and Radiation Safety Section were generally effective in performing their licensing, registering, and monitoring functions of medical first responders, life support agencies and life support vehicles, and x-ray machines and facilities. Our assessment disclosed reportable conditions* related to data systems, licensing of clinical laboratories, assessment of emergency medical services, and registration of radiation machines (Findings 2 through 5).

Noteworthy Accomplishments: In October 2001, BHS entered into a joint project with the Renal Network of the Upper Midwest, Inc., with the overall goal to improve the end stage renal disease (ESRD) patient care system. This collaborative effort was the result of recommendations made by the federal Office of the Inspector General in its external quality review of dialysis facilities.

BHS stated that the accomplishments of this project include an improved ESRD patient complaint processing system that includes both agencies working together to evaluate and act on patient complaints and grievances; to develop policies and procedures for evaluating, referring, and collaborating on patient complaints; and to identify and

* See glossary at end of report for definition.

develop opportunities to improve the response to patient complaints. BHS stated that the ongoing joint project has helped to improve the effectiveness and efficiency in recording, evaluating, and responding to ESRD patient complaints.

FINDING

1. Monitoring of Licensed Health Care Facilities

BHS did not sufficiently survey or inspect hospices, FSOFs, substance abuse treatment programs, and hospice residences. Also, BHS had not established formal policies and procedures to effectively prioritize and schedule required surveys and inspections of licensed health care facilities.

Conducting annual and biennial surveys and inspections in a timely manner would help to ensure that licensed health care facilities are operating in substantial compliance with State laws and administrative rules. In addition, the development of formal policies and procedures for prioritizing and scheduling surveys and inspections would help ensure that those facilities with the greatest risk would be adequately monitored.

Section 333.20155(1) of the *Michigan Compiled Laws* requires visits to each hospice and FSOF at least annually for the purposes of survey, evaluation, and consultation. *Michigan Administrative Code R 325.14205(1)* requires the completion of an inspection of a substance abuse treatment program prior to the issuance of an annual license. Section 333.20155(2) of the *Michigan Compiled Laws* requires a visit to each hospice residence at least biennially for the purposes of survey, evaluation, and consultation.

Examples of items included in a BHS survey or inspection of a licensed health care facility may include the review of: medical policies and procedures; patient medical records; physical plant; housekeeping functions; disaster and emergency procedures; physician, nurse and other professional staff educational and training qualifications; and medication storage.

We analyzed the status of the most recent surveys and inspections conducted for each of the licensed facilities. BHS or medical accreditation organizations completed surveys of hospitals and BHS completed surveys for psychiatric hospitals, programs, and units within *Michigan Compiled Law* requirements. However, we noted that a substantial number of annual and biennial surveys and

inspections were overdue for hospices, FSOFs, substance abuse treatment programs, and hospice residences. The following table shows, as of August 31, 2003, the number of facilities and the amount of time since the last survey or inspection was completed:

Amount of Time Since the Last Survey or Inspection	Hospices (1)	FSOFs (1)	Substance Abuse Treatment Programs (1)(2)	Hospice Residences (3)
Surveys/Inspections Completed on Time:				
Within 1 year	0	5	258	0
More than 1 year but less than 2 years				0
Surveys/Inspections Overdue:				
More than 1 year but less than 2 years	0	8	499	
More than 2 years but less than 3 years	0	1	1	0
More than 3 years but less than 4 years	7	4	0	0
More than 4 years but less than 10 years	67	27	0	1
Greater than 10 years	31	1	0	0
No survey or inspection date recorded	20	31	0	6
Total	<u>125</u>	<u>77</u>	<u>758</u>	<u>7</u>

- (1) Annual survey or inspection required.
- (2) Table includes only substance abuse treatment programs, i.e., outpatient, outpatient methadone, residential, residential detoxification, and inpatient facilities. Table does not include substance abuse prevention and court designated programs.
- (3) Biennial survey required.

As shown in the table, our review disclosed several facilities for which no survey or inspection dates were recorded in BHS's facility tracking system. BHS stated that most likely no surveys or inspections were performed for those facilities since the implementation of its data system in 1994, and the system was not updated to include survey or inspection dates occurring prior to its implementation.

BHS has given higher priority for the survey and certification of health care facilities receiving federal Medicare and Medicaid funding in accordance with national priorities. Such priorities decrease the available BHS resources to monitor State licensed health care facilities.

RECOMMENDATIONS

We recommend that BHS sufficiently survey or inspect hospices, FSOFs, substance abuse treatment programs, and hospice residences.

We also recommend that BHS establish formal policies and procedures to effectively prioritize and schedule required surveys and inspections of licensed health care facilities.

AGENCY PRELIMINARY RESPONSE

BHS agrees with the finding and both recommendations. BHS noted that the State's current operating environment contributed to its inability to perform the required surveys in a timely manner as required by State laws and administrative rules. Subsequent to the audit period, BHS informed us that it has been able to increase its staffing levels and is now meeting the statutorily required licensing requirements. BHS will also update its current policies and procedures to reflect the scheduling priorities for the survey of these facilities. These policies should be developed by March 2005.

With respect to the surveys of FSOFs, BHS informed us that a self-evaluation inspection form was sent to each licensed facility to assess the facilities' compliance with applicable State statutes. Ninety-eight percent of the facilities surveyed responded in a timely manner to the evaluation, providing BHS with an overall self-assessment of their compliance with State statutes.

FINDING

2. Data Systems

BHS's Care*Net data system and substance abuse computer information data system contained inaccurate information. Maintaining accurate data systems would help BHS to effectively monitor health care facilities to ensure compliance with licensing and inspection requirements.

BHS's Division of Licensing and Certification is responsible for licensing, surveying, and monitoring approximately 3,000 health care facilities located throughout the State. These facilities include ambulatory surgical centers; clinical laboratories; comprehensive outpatient rehabilitation facilities; ESRD facilities; FSOFs; home health agencies; hospices; hospice residences; hospitals; outpatient physical therapy facilities; portable x-ray facilities; psychiatric hospitals, programs, and units in general hospitals; rural health clinics; and substance abuse programs. The Division's central office and program managers rely on information obtained from

computer-generated reports to monitor program activities and to track compliance with required licensing and survey requirements.

Our review of BHS's data systems disclosed the following deficiencies:

- a. Numerous errors existed in recording survey dates on reports generated from the Care*Net data system. The Care*Net data system is an automated information database used to record and track health care facility licensing and survey information. Our review of the Care*Net data system disclosed that no BHS surveys were completed for 49 (28%) of the 178 licensed hospitals. However, a review of licensing files noted that 44 of those hospitals had received surveys by BHS between 1987 and 2003. In addition, for a sample of 25 hospitals with BHS survey dates recorded in the Care*Net data system, 6 (24%) survey dates recorded were incorrect. Hospitals receive a biennial survey from either BHS or an approved medical accreditation organization. In addition, BHS is required to perform approximately 8 hospital surveys per year to validate the results of surveys completed by approved medical accreditation organizations.
- b. Information in BHS's substance abuse computer information database, used to document the inspection of substance abuse treatment programs, was not always accurate.

We reviewed a sample of 30 substance abuse treatment program facility licensing files coded in the database as having received an on-site inspection. However, our review noted that 11 (37%) of the facilities did not receive an on-site inspection, but instead received only a desk audit. Desk audits primarily consist of scanning facility licensing files maintained at BHS and do not include an on-site inspection.

In addition, we noted that the substance abuse computer information database recorded 27 on-site facility inspections as completed on February 6, 2003. This number of facility inspections could not be accurate because BHS had only one examiner available to perform inspections and BHS stated that its examiner could only perform two inspections per day. Inaccurate information contained in this database could result in BHS's failure to sufficiently inspect substance abuse treatment program facilities.

RECOMMENDATION

We recommend that BHS ensure that its Care*Net data system and substance abuse computer information data system contain accurate information.

AGENCY PRELIMINARY RESPONSE

BHS agrees with the finding and corresponding recommendation. BHS informed us that it has implemented procedures to ensure that data entered into the Care*Net data system and the substance abuse computer information data system is accurate.

FINDING

3. Licensing of Clinical Laboratories

BHS had not assessed all clinical laboratories to determine if they fall under State licensing requirements. Consequently, BHS had not licensed any clinical laboratories, as required by State law. BHS had not licensed clinical laboratories because it relies on federal certification of these facilities. However, BHS had not obtained amendatory legislation to modify State licensure requirements to allow for reliance on federal clinical laboratory certification procedures, if such certification fulfills State licensing requirements.

Because BHS had not licensed clinical laboratories or documented that federal clinical laboratory certification procedures satisfy State licensing requirements, BHS cannot ensure that all clinical laboratories requiring a State license are properly monitored and operating in compliance with State law.

A clinical laboratory is any facility that conducts examinations of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of or the assessment of the health of human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

Section 333.20511 of the *Michigan Compiled Laws* requires that clinical laboratories be licensed and that visits be made at least biennially to the laboratories for the purpose of survey, evaluation, and consultation. State law exempts certain types of clinical laboratories from licensure requirements, such as

laboratories operated by an individual licensed to practice medicine or dentistry who performs laboratory tests for treatment of the licensee's patients, laboratories operated by a group of not more than five individuals licensed to practice medicine or dentistry, laboratories operated by a college or university for training of students, or laboratories operated by the federal government.

In addition to State law, clinical laboratories also fall under federal regulation. The federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) require laboratories, including physician office laboratories, to meet applicable federal requirements and to have a CLIA certificate in order to operate. In addition, CLIA requires that laboratories performing tests of moderate and/or high complexity to receive an on-site survey every two years.

BHS did not license clinical laboratories operating in Michigan, stating that the CLIA certification standards are comparable to the State licensing requirements and that requiring the State to license these laboratories would result in a duplication of effort. However, CLIA and State law requirements are not consistent as to which types of facilities require biennial on-site surveys.

According to federal records, there are approximately 6,200 clinical laboratories operating in the State, all of which have been certified in accordance with CLIA standards. Approximately 1,100 of these laboratories have received an on-site survey in accordance with CLIA standards performed by BHS or various medical accreditation organizations.

However, BHS had not conducted an assessment of the remaining 5,100 clinical laboratories to determine if they fall under State licensing requirements, which would require the laboratories to receive a biennial on-site visit for the purpose of survey, evaluation, or consultation.

RECOMMENDATIONS

We recommend that BHS assess all clinical laboratories to determine if they fall under State licensing requirements and license clinical laboratories, as required by State law.

We also recommend that BHS obtain amendatory legislation to modify State licensing requirements to allow for reliance on federal clinical laboratory certification procedures, if such certification fulfills State licensing requirements.

AGENCY PRELIMINARY RESPONSE

BHS agrees with the finding and both recommendations. However, while agreeing in principle with the first recommendation, BHS stated that it does not have the ability under the current environment to assess all of the clinical laboratories to determine if they fall under State licensing requirements. BHS informed us that the State licensure laws have not been enforced because they are vastly less comprehensive in oversight of laboratory testing. CLIA requires that virtually all laboratories, including physician office laboratories, meet applicable federal requirements and have a CLIA certificate in order to operate. BHS maintains that the health and safety of those relying on these laboratories will not be compromised because the CLIA program requirements are much more stringent than the State licensure requirements. In addition, under the current licensure requirements and definitions, BHS estimates that only a few hundred laboratories of the 5,200 unlicensed laboratories would require licensure.

With respect to the second recommendation, BHS will renew its previous efforts to have the licensure laws rescinded. BHS will work through the Health Policy, Regulation, and Professions Administration and coordinate its activities with the Attorney General, if necessary, to draft legislation that would repeal the State licensure program. BHS expects to initiate this action immediately.

FINDING

4. Assessment of Emergency Medical Services (EMS)

BHS had not established a process to assess the need for and quality of EMS throughout the State, as required by State law.

Because EMS operations are performed throughout the State, establishing a process to assess EMS would assist BHS in evaluating program and provider performance, identifying problems, and initiating suggestions for program improvements.

Section 333.20910(1)(a) of the *Michigan Compiled Laws* states that the department is responsible for the development, coordination, and administration of a Statewide EMS system. In addition, Section 333.20910(1)(i) of the *Michigan Compiled Laws* requires that the department collect data, as necessary, to assess the need for and quality of EMS throughout the State. BHS stated that it has not performed EMS data collection and analysis functions because of the lack of staffing resources.

BHS is responsible for the licensure of approximately 800 medical first responder and life support agencies and approximately 2,700 life support vehicles. Medical control authorities established in each county or group of counties are responsible for establishing policies, procedures, and protocols on how prehospital emergency care is to be carried out within their particular geographic areas.

BHS has assembled a prehospital data task force and is assessing a process for data collection and evaluating data elements to include in its data collection system that would benefit its monitoring efforts. Examples of data elements being considered for collection include: the EMS vehicle dispatch time and time of arrival at the emergency scene; the time the EMS unit left the emergency scene and the amount of time to transfer the patient to his/her destination; and a description of the patient's injuries and the types of care provided.

RECOMMENDATION

We recommend that BHS establish a process to assess the need for and quality of EMS throughout the State, as required by State law.

AGENCY PRELIMINARY RESPONSE

BHS agrees with the finding and recommendation. The Emergency Medical Services Section currently has a prehospital data task force that is looking at all the data elements prescribed by the National Highway Traffic Safety Administration, which every State must incorporate into its design. In addition, BHS informed us that it has just recently concluded a review of the optional items, which are being considered as additional Michigan specific requirements.

BHS stated that while federal dollars were available at the local level to develop prehospital data system software, the project has been slow to materialize because of funding and staffing availability at the State level. In addition, the task of designing and collecting data for a project of this magnitude has been extremely

difficult. Notwithstanding the problems encountered with the data collection phase, BHS informed us that it has made considerable progress in the initial phase of the project. BHS is optimistic that the Department of Community Health will ensure that adequate resources and support are provided to ensure that the project is completed successfully.

FINDING

5. Registration of Radiation Machines

BHS needs to improve its controls to ensure that radiation machines are properly registered and monitored as required by the *Michigan Administrative Code*. This would help ensure that radiation machines are functioning in a manner that will protect the health and safety of patients and users of the machines.

Michigan Administrative Code R 325.5181 requires that a person shall not manufacture, produce, transport, own, receive, acquire, possess, use, or transfer any radiation machine unless registered or exempted. Also, *Michigan Administrative Code* R 325.5195 requires anyone who sells, transfers, lends, assembles, or installs a radiation machine in Michigan to submit quarterly reports to BHS, noting those facilities that received radiation machines. In addition, *Michigan Administrative Code* R 325.5603 requires the inspection of mammography machines no later than 60 days after initial authorization and annually thereafter.

The registration of radiation machines helps ensure that each machine and its users are subject to monitoring by BHS. Such monitoring would help ensure that the radiation machines are functioning as intended and that the machines are operated by individuals who are knowledgeable concerning the hazards of handling equipment utilizing radioactive and other sources of ionizing materials.

BHS procedures for registering radiation machines include comparing radiation machines noted on the installers' quarterly reports to machines listed in BHS's radiation machine registration database. However, BHS verifies only that the facility receiving the new radiation machine is registered in the database; BHS does not verify the actual registration of the new machine. BHS estimates that it registers 1,700 new radiation machines each year and believes that it would be too time-consuming to verify the registration of each new machine. BHS instead relies

on facilities to self-report the installation of new radiation machines during the facilities' annual registration. In addition, BHS relies on its inspectors to identify unregistered machines during annual mammography facility inspections or during the nonmammography radiation facility inspections completed once every five years.

We reviewed a sample of 35 radiation machines that were recorded on installers' quarterly reports and noted 8 (23%) machines that were not registered with BHS. The unregistered machines were installed from 11 to 17 months prior to our review, and none of the facilities reported the new machines on their current annual registrations. The results of our sample indicate that BHS procedures are not sufficient to ensure the registration of all radiation machines.

RECOMMENDATION

We recommend that BHS improve its controls to ensure that radiation machines are properly registered and monitored as required by the *Michigan Administrative Code*.

AGENCY PRELIMINARY RESPONSE

While BHS agrees with the finding and the recommendation in general, BHS stated that it simply does not have the resources to verify the registration of each new machine. Because of the sheer volume of new machines, BHS's Radiation Safety Section only has the ability to review installers' quarterly reports to ensure that facilities at locations listed in the reports have a valid radiation machine registration with the State of Michigan. In any cases in which there is no registered facility at the location listed on a report, appropriate action would be taken to get the facility registered.

As pointed out in the audit, BHS noted that reviewing machine-specific information for each registered facility listed in the installers' quarterly reports would be extremely labor intensive. Michigan has over 9,000 registered radiation facilities, many of which have large numbers of x-ray machines in use. For these facilities, a detailed review of the machines they have registered and our subsequent follow-up action, while of benefit in ensuring accurate registrations of x-ray machines, would require considerable staff time.

BHS noted that it is also important to recognize that any registration certificate changes that should be made, including changes at registered facilities that obtained new equipment, are ultimately noted during the routine on-site safety inspections of x-ray facilities. All facilities receive periodic inspections. In most cases, registered facilities will request their registration to be updated when they obtain new x-ray equipment. In the cases when that does not happen promptly, any unregistered machines are discovered when on-site inspections are conducted. These procedures provide assurances that no machines remain unregistered for more than five years, with most being discovered much sooner.

EFFECTIVENESS AND EFFICIENCY IN PROCESSING CONSUMER COMPLAINTS

COMMENT

Audit Objective: To assess BHS's effectiveness and efficiency in processing consumer complaints.

Conclusion: We concluded that BHS was generally effective and efficient in processing consumer complaints. Our report does not include any reportable conditions related to this audit objective.

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SUPPLEMENTAL INFORMATION

UNAUDITED

BUREAU OF HEALTH SYSTEMS
 Department of Community Health
 Summary Schedule of Licensed and Certified Facilities by Type
As of September 2003

<u>Facility Type</u>	<u>Licensed Facilities</u>	<u>Certified Facilities</u>
Ambulatory surgical centers		3
Clinical laboratories		387
Comprehensive outpatient rehabilitation facilities		27
End stage renal disease facilities		143
Freestanding surgical outpatient facilities	77	
Home health agencies		276
Hospices	125	
Hospice residences	7	
Hospitals	178	
Outpatient physical therapy facilities		377
Portable x-ray facilities		24
Psychiatric hospitals, programs, and units	60	
Rural health clinics		168
Substance abuse programs:		
Treatment programs	758	
Prevention and court designated programs	<u>402</u>	
 Total	 <u>1,607</u>	 <u>1,405</u>

GLOSSARY

Glossary of Acronyms and Terms

BHS	Bureau of Health Systems.
CLIA	federal Clinical Laboratory Improvement Amendments of 1988.
effectiveness	Program success in achieving mission and goals.
efficiency	Achieving the most outputs and outcomes practical with the minimum amount of resources.
EMS	emergency medical services.
ESRD	end stage renal disease.
FSOF	freestanding surgical outpatient facility.
material condition	A reportable condition that could impair the ability of management to operate a program in an effective and efficient manner and/or could adversely affect the judgment of an interested person concerning the effectiveness and efficiency of the program.
mission	The agency's main purpose or the reason that the agency was established.
performance audit	An economy and efficiency audit or program audit that is designed to provide an independent assessment of the performance of a governmental entity, program, activity, or function to improve public accountability and to facilitate decision making by parties responsible for overseeing or initiating corrective action.

reportable condition

A matter that, in the auditor's judgment, represents either an opportunity for improvement or a significant deficiency in management's ability to operate a program in an effective and efficient manner.