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– Article IV, Section 53 of the Michigan Constitution

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August 16, 2005

Ms. Norma Hagenow, Chairperson
Certificate of Need Commission
and
Ms. Janet Olszewski, Director
Department of Community Health
Lewis Cass Building
Lansing, Michigan

Dear Ms. Hagenow and Ms. Olszewski:

This is our report on our follow-up of the 3 material findings (Findings 1, 3, and 5) and 5 corresponding recommendations reported in the performance audit of the Certificate of Need Program, Certificate of Need Commission, Department of Community Health. That audit report was issued and distributed in April 2002; however, additional copies are available on request or at <<http://www.audgen.michigan.gov>>.

Our follow-up disclosed that the Department of Community Health had initiated corrective action but either had not complied or had not substantially complied with any of the recommendations.

If you have any questions, please call me or Scott M. Strong, C.P.A., C.I.A., Deputy Auditor General.

AUDITOR GENERAL

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**CERTIFICATE OF NEED PROGRAM
CERTIFICATE OF NEED COMMISSION
DEPARTMENT OF COMMUNITY HEALTH
FOLLOW-UP REPORT**

INTRODUCTION

This report contains the results of our follow-up of the material findings and corresponding recommendations and the agency's preliminary response reported in the performance audit of the Certificate of Need (CON) Program, CON Commission, Department of Community Health (DCH) (#3964401), which was issued and distributed in April 2002. The performance audit contained 3 material findings (Findings 1, 3, and 5) and 2 other reportable conditions.

PURPOSE OF FOLLOW-UP

The purpose of this follow-up was to determine whether DCH had taken appropriate corrective measures in response to the 3 material findings and 5 corresponding recommendations.

Prompt and thorough compliance with the recommendations is essential to help ensure that the Certificate of Need Program is achieving its objectives and fulfilling DCH's mission in an effective and efficient manner.

BACKGROUND

DCH administers the CON Program, which was originally established in Michigan by Act 256, P.A. 1972. The CON Program is intended to regulate the health care industry in Michigan by balancing cost, quality, and access issues and ensuring that only needed health care services are developed.

The CON Commission was created within the Department of Public Health (DPH) by Act 332, P.A. 1988 (the CON Reform Act of 1988). Executive Order No. 1996-1,

effective April 1, 1996, created DCH and transferred duties and responsibilities for the CON Program from DPH to DCH. Pursuant to an amendment to CON laws in 2002, the CON Commission increased from 6 members to 11 members appointed by the Governor with the advice and consent of the Senate. The CON Commission members are responsible for developing proposed CON review standards and proposing modifications in the statutory list of covered medical services. DCH provides administrative support to the CON Commission and carries out the day-to-day operations of the CON Program. This includes approving, disapproving, or approving with conditions or stipulations CON applications consistent with the review standards.

SCOPE

Our fieldwork was conducted in March and April 2005.

We reviewed DCH policies and procedures to determine whether they had changed since our audit. We interviewed DCH personnel and performed various tests to determine whether the corrective action that was taken to comply with the recommendations related to our material findings was working as DCH had intended.

FOLLOW-UP RESULTS

EFFORTS TO EVALUATE THE PERFORMANCE OF THE CON PROGRAM

FINDING

1. Evaluation of the CON Program

RECOMMENDATION

We recommend that DCH, in conjunction with the CON Commission, evaluate the CON Program in order to determine whether the CON Program is achieving its goal of balancing cost, quality, and access issues and ensuring that only needed services are developed in Michigan.

AGENCY PRELIMINARY RESPONSE

DCH

DCH agrees with the recommendation and, in consultation with the CON Commission, will enhance existing processes in order to determine whether the CON Program is achieving its goal of balancing cost, quality, and access issues and ensuring that only needed services are developed in Michigan.

DCH will contract with an independent outside contractor to conduct a comprehensive evaluation of the CON Program. This study will assist DCH in determining more meaningful, quantifiable measures for assessing the CON Program. These measures will be incorporated in future iterations of the CON Program Annual Activity Report. Moreover, this comprehensive evaluation will assist the CON Commission in making recommendations to the Senate and House of Representatives committees regarding the CON Program, as required in Section 333.22215(1)(f) of the *Michigan Compiled Laws*.

The comprehensive evaluation will examine if the CON Program is meeting its stated goals and objectives and include a critical review of the relevance of current thresholds and standards. The evaluation will also provide recommendations to improve processes and alternative models to achieve the CON Program's stated goals and objectives.

DCH will provide to the CON Commission evaluation information and, when available, the findings and recommendations to assist in its report to the Legislature, as required in Section 333.22215(1)(f) of the *Michigan Compiled Laws*.

DCH will strengthen the CON Program Annual Activity Report, based in part from information gained through the comprehensive evaluation. This report is submitted annually to the CON Commission in order for it to assess the operations and effectiveness of the CON Program, as required in Section 333.22215(1)(e) of the *Michigan Compiled Laws*. Report improvements will include additional output and outcome measurements that can be used to evaluate, monitor, and ensure compliance of the CON Program. DCH also will work with the Department of Management and Budget and, when appropriate, with the Department of Consumer and Industry Services to evaluate and develop a corrective action plan to improve the CON Program's current management information systems for tracking CON Program activity. In addition, DCH will work to improve its data information systems to ensure that appropriate, accurate, and up-to-date data are available to assess the ongoing effectiveness of the CON Program.

CON COMMISSION

The CON Commission agrees with the recommendation and believes that the lack of the statutorily required information from DCH staff on CON Program operations is a serious issue. The CON Commission is dependent on the information from DCH to fulfill its statutory responsibilities to provide both the annual review of CON Program operations and recommendations at least every five years to the Legislature on the future of the Program, including changing the list of covered services. The CON Commission informed us that recently, in order to still meet its responsibilities, it was able to convene a voluntary special task force, which resulted in the CON Commission recommending the deregulation of partial day psychiatric programs (which the Legislature has allowed to go forward) and the prioritization of needed changes in CON review standards. The CON Commission stated that the successful update process would have worked far better if DCH had been able to provide the periodic information on program performance, as required by statute, and hopes that can be done in the future.

The CON Commission informed us that having an independent outside contractor conduct a comprehensive evaluation of the CON Program has been suggested to it before, sometimes through public comment. The CON Commission hopes that the Legislature will support this idea of having such an evaluation done and thinks that

it would be most valuable if the specifications of the contract were developed after consultation and agreement among the legislative health committees, DCH, and the CON Commission and after receiving public input. That would facilitate the outside contractor's report covering issues of particular concern to the Legislature, the CON Commission, DCH, and the public.

FOLLOW-UP CONCLUSION

DCH had initiated limited corrective action but had not yet complied with this recommendation.

DCH commissioned an independent evaluation of the CON Program in July 2002. One purpose of the evaluation was to assess the CON Program's success in meeting its stated program goal of balancing cost, quality, and access issues and ensuring that only needed services are developed in Michigan. In addition, DCH intended to use information gained through the comprehensive evaluation to strengthen its CON Program Annual Activity Report that the CON Commission adopts as its statutorily required annual assessment of the operations and effectiveness of the CON Program.

The evaluation report, dated May 2003, did not conclude whether the CON Program was achieving its stated program goal. DCH informed us that it was developing performance measures for the CON Program staff with goals related to processing applications, performing follow-up application, and processing Freedom of Information Act (FOIA) requests, but DCH had not developed quantifiable goals and objectives to help in evaluating the overall performance of the CON Program.

DCH also had not implemented improvements to its management information system that gathers relevant data to measure CON Program performance and to compare performance against desired outputs and outcomes. DCH informed us that it had initiated a contract with the Department of Information Technology in September 2002 to improve its management information system. DCH expected these improvements to be implemented by summer 2005 at the earliest.

In addition, DCH had not strengthened the CON Program Annual Activity Report by including output and outcome measures that could be used to evaluate, monitor, and ensure compliance of the CON Program. These reports presented application

activities outputs and a brief summary of CON Commission activities but still did not serve as an evaluation of the performance of the CON Program.

CON APPLICATIONS

FINDING

3. Monitoring of Approved CON Projects

RECOMMENDATIONS

We recommend that DCH improve its efforts to monitor projects that received an approved CON to help ensure that the projects are completed within the allowed time frames.

We also recommend that DCH ensure that facilities submit required documentation related to CON applications and project contracts on a timely basis.

AGENCY PRELIMINARY RESPONSE

DCH agrees with the recommendations and will improve and clarify procedures to monitor projects that received an approved CON to help ensure that the projects are completed within the allowed time frames. DCH will also ensure that facilities submit required documentation relating to CON applications and project contracts on a timely basis.

Currently, DCH notifies the applicant in the CON decision letter that it must provide the required notice within 10 days of completion or not later than 12 months from the date of the approval of the CON, whichever occurs first. DCH informed us that most applicants do not follow the 10-day completion notice requirement and, instead, respond to the letter sent to them by DCH during the 11th month. Consequently, DCH believes that noncompliance with the 10-day notice requirement should not warrant compliance action and that this requirement adds minimal value to the CON Program. Therefore, DCH will make a recommendation to the CON Commission at the next meeting scheduled in June 2002 to remove this provision in the standard. DCH will continue to initiate follow-up in the 11th month after CON approval.

Additionally, in order to minimize interpretation of terminology, DCH will clarify and define various terms in the applicable departmental form(s). Finally, DCH will establish formal written policies and procedures documenting appropriate follow-up activity that must occur and the methodology for each. These changes will be implemented by June 30, 2002.

FOLLOW-UP CONCLUSION

DCH had initiated corrective action but had not yet substantially complied with these recommendations.

DCH updated various checklists and form letters for following up on approved projects more timely and helping ensure that standard documentation is obtained. In addition, a new form letter was created to help obtain documentation for completed projects. However, DCH had not developed formal policies or procedures for monitoring approved projects.

The number of approved CON project applications had increased from 479 during the three-year period January 1, 1999 through December 31, 2001 to 770 approved CON applications during the three-year period January 1, 2002 through December 31, 2004. As a result, the listing of CON projects that needed follow-up action had increased from 256 CON projects at the time of our audit to 434 at the time of our follow-up.

Our review disclosed that DCH had sufficiently monitored CON projects that were completed within one year of the date of the approval of the CON. However, DCH had not improved its monitoring of CON projects that were not completed within one year of the date of the approval of the CON. We selected 3 CON projects that had not been completed within one year of the date of the approval of the CON and determined that DCH had not completed sufficient monitoring of these 3 projects to ensure that these projects were completed within the allowed time frames or that required documentation relating to the approved CON's was submitted on a timely basis.

DCH requires facilities to complete and return a project implementation progress report (PIPR) within 12 months of project approval. DCH continues to use PIPRs to help determine the status of a CON project and to help determine when facilities are required to submit additional information in order to satisfy the requirements of

their CON. CON projects that extend over a period of more than one year may be required to submit several PIPR forms.

For the 3 projects we reviewed, DCH had approved the CON in September 2003, May 2001, and August 1998, respectively. However, as of the date of our review, DCH had not performed any follow-up monitoring of these projects for 562 days, 763 days, and 765 days, respectively. Further, DCH did not ensure that these facilities had submitted the required documentation related to their CON applications in a timely manner. The facility whose CON was approved in August 1998 had submitted an interim PIPR on March 25, 2003 that indicated the project was 99% complete. The other two facilities had not submitted any interim PIPRs.

COMPLIANCE WITH APPLICABLE CON PROVISIONS

FINDING

5. Monitoring Compliance With CON Review Standards

RECOMMENDATIONS

We recommend that DCH implement effective policies and procedures to obtain relevant data needed to monitor facilities' compliance with quality assurance requirements contained in CON review standards.

We also recommend that DCH take appropriate remedial action for facilities identified as not being in compliance with quality assurance requirements.

AGENCY PRELIMINARY RESPONSE

DCH

DCH agrees with the recommendations and will develop and implement effective policies and procedures to obtain relevant data needed to monitor facilities' compliance with quality assurance requirements contained in the CON review standards. When necessary, DCH will take appropriate remedial action for facilities identified as not being in compliance with quality assurance requirements.

DCH will ensure facility compliance through a three-pronged approach: 1) surveillance, 2) proactive compliance checks, and 3) compliance investigations. As part of the surveillance effort, DCH administers an annual hospital survey to

request data that it uses to monitor compliance with the CON review standards' quality assurance requirements. DCH informed us that it has already initiated improvements to this surveillance tool to address missing data that has not been previously collected - open-heart surgery and cardiac catheterization. DCH informed us that this has been corrected as of March 2002 and that all relevant data needed to monitor the quality assurance requirements will be collected, as requested in the 2001 annual hospital survey. In addition, DCH will initiate formal written procedures to review and verify that current surveillance tools capture all relevant data needed for compliance verification when CON review standards are updated.

DCH informed us that it also monitors compliance with quality assurance requirements on a proactive basis and that this is done through its review of quality assurance requirements when a CON application is received, reviewed, and processed. If applicable quality assurance requirements are not met, the CON application is either denied or approved with conditions.

Additionally, DCH informed us that, as required by statute, compliance investigation always occurs when DCH receives a written complaint of potential noncompliance. If an applicant appears to be in noncompliance, DCH will initiate a desk audit and, if needed, assist the applicant to bring itself into compliance. If the desk audit appears to confirm noncompliance, a recommendation pursuant to statutory allowances will be forwarded to DCH's compliance officer.

DCH maintains a log of all compliance actions. Additionally, DCH informed us that, in January 2002, it instituted a tracking process for all desk audit activities. Finally, all quality assurance compliance processes will be documented by June 30, 2002 in formal written departmental policies and procedures. All compliance actions will be reported in aggregate form in the CON Program Annual Activity Report.

CON COMMISSION

The CON Commission agrees with the recommendations and informed us that it is keenly aware that staff shortages affect the possibility of post-approval monitoring of CON projects and that the ongoing monitoring of CON-approved projects has long been a particular concern of the CON Commission. The CON Commission believes that compliance information is critical to ensure that recipients of CON approvals are actually meeting the quality standards, not just in the first year but thereafter.

The CON Commission informed us that the 2000 annual hospital survey is not yet available to the CON Commission or the public and that the 2001 report is also still being processed. Without these ongoing reports, the CON Commission cannot begin to evaluate whether consumers are receiving the promise of quality that is part of the CON Program objectives, not to mention timely access to services. The CON Commission believes that the audit's specific suggestions for improving the annual survey were also quite helpful. The CON Commission informed us that it needs the revised annual hospital survey data, and other sources of follow-up information, to properly determine if changes should be made in the quality assurance requirements in future iterations of the CON review standards.

The CON Commission believes that providing this information on a timely basis is an objective that current DCH staff have not been able to fully meet because of staff shortages. The CON Commission informed us that the concern about monitoring of quality compliance is an issue that has been raised by the CON Commission for years. The CON Commission hopes that DCH can now institute processes to fulfill the quality monitoring and other deficiencies identified in the audit. The CON Commission's concern is how that responsibility will be fulfilled on an ongoing basis once these "processes" have been established.

FOLLOW-UP CONCLUSION

DCH had initiated corrective action but had not yet substantially complied with these recommendations.

We reviewed the hospital survey document administered by DCH during fiscal year 2003-04 and determined that DCH had corrected some of the survey deficiencies identified in the audit. Improvements to the survey included requesting the number of procedures performed by each physician for open-heart surgery and cardiac catheterization services. In addition, the survey now requests the route number for mobile lithotripsy services so that the number of procedures performed by each unit can be determined. However, the survey still did not capture all the data necessary to determine a facility's compliance with the following CON review standards: transplants, megavoltage radiation therapy (MRT), and nursing home/hospital long-term care beds.

DCH performed a Statewide compliance review of Adult Open Heart Surgery Services Utilization in September 2004. Based on this review, DCH initiated

remedial action for facilities identified as not being in compliance with project delivery requirements that are intended to help ensure the quality of the services being provided. DCH had not performed a similar review of the other review standards that contain project delivery requirements. We reviewed reports compiled by DCH from the 2003 annual hospital surveys and noted that 19 (31%) of 62 facilities did not meet minimum project delivery requirements for MRT and that 12 (9%) of 137 facilities providing computed tomography services did not meet minimum project delivery requirements. Project delivery information for surgical, cardiac catheterization, and pancreas transplant services was not readily available from DCH, but DCH informed us it is likely that facilities continue to fall below the project delivery standards for those services. DCH had not taken remedial action against any of these facilities.

