NO. 2000-4068-3

INDEPENDENT STATE AUDITOR'S REPORT ON THE ADMINISTRATION AND OVERSIGHT
BY THE DEPARTMENTS OF PUBLIC HEALTH, MENTAL HEALTH, AND MENTAL RETARDATION
OF THE MEDICATION ADMINISTRATION PROGRAM
AT 48 COMMUNITY RESIDENCES AND 12 HUMAN SERVICE PROVIDERS

OFFICIAL AUDIT REPORT
SEPTEMBER 28, 2001
INTRODUCTION

On November 18, 1988, the Office of State Auditor issued an audit report (No. 87-1080-3) entitled “Report on the Activities of the Department of Mental Health’s Licensing Division.” This report disclosed that unlicensed and untrained individuals were administering medications to consumers in community-based programs (i.e., residences and group homes overseen by the Department of Mental Health (DMH) and the Department of Mental Retardation [DMR]). This practice was contrary to Chapter 94C of the Massachusetts General Laws, which authorizes only licensed individuals (e.g., medical doctors and nurses) to administer medication.

In August 1993, the Department of Public Health (DPH), under authority granted to it under Chapter 94C, promulgated 105 Code of Massachusetts Regulations 700.003, which authorized certain groups of nonlicensed individuals to administer medication in these programs, provided that certain requirements were met. These requirements included the successful completion of the Medication Administration Program (MAP), which provided training and certification to service provider direct care staff working in residential programs. Since MAP’s implementation through December 31, 1999, 31,308 individuals have been certified by DMH and DMR to administer medication to 11,547 individuals residing in community-based residences operated by DMH and DMR.

Our audit was conducted to assess certain aspects of MAP at DPH, DMH, and DMR. Our specific audit objectives were to: (1) obtain an understanding of how MAP is currently being administered; (2) determine the current status of MAP as a result of the recommendations and improvements made by other agencies and legislative bodies; (3) perform audit testing at the administrative offices of DPH, DMR, and DMH and various community-based residences in order to assess the effectiveness and efficiency of these agencies’ administrative and operational activities relative to MAP; (4) assess the adequacy of the systems established by DPH for measuring, monitoring, and reporting the program’s effectiveness; (5) review the dispensing of medication at certain programs to determine whether it is being done in a manner consistent with applicable laws and regulations; and (6) if applicable, make recommendations on how to improve MAP.

Our audit revealed that the establishment of MAP was a positive step toward improving the manner in which medications are administered to individuals in DMH and DMR community-based residences. However, we noted deficiencies in the administration and oversight of the program that could jeopardize the quality of care that consumers receive in these residences, as detailed in the Audit Results section of this report.

AUDIT RESULTS

1. **Deficiencies Found in MAP Medication Occurrence Reporting Process**: We noted several deficiencies in the Medication Occurrence Reporting (MOR) process utilized by DMH and DMR. Specifically, our audit noted that (1) contracted service providers in 40%-71% of the records we reviewed did not report in writing all incidences of medication administration errors to their state purchasing agencies within the timeframe established by MAP policies, (2) contracted service providers in 57%-68% of the records we reviewed did
not report medication administration errors that resulted in medical intervention (e.g., hospitalization) within 24 hours as required by MAP policies, and (3) MORs were not effectively utilized to ensure that individuals who made medication errors were identified and properly trained to prevent future medication errors.

2. **The MAP Monitoring Process Needed Improvements:** Our review noted that DPH’s monitoring of the MAP process needed improvement. According to state regulations, DPH is authorized to perform clinical reviews of community-based programs to inspect client records pertaining to the use and administration of prescription medications. However, DPH has assigned only one person to review approximately 250 community-based programs involving 2,441 sites. Since the inception of the clinical review process to the end of our audit period, only 43 (17%) of the community-based programs involving 138 (6%) sites had been reviewed. Also, DPH did not have written policies and procedures detailing when and how clinical reviews are to be conducted (e.g., plans for selection of programs for review, how reviews are conducted, types of records/files to be examined, personnel to be interviewed). As a result, the Commonwealth cannot be assured that consumers in the DMH and DMR community-based programs are administered medications in the most safe and consistent manner. During our audit, we visited 48 community residences funded by DMH, DMR, and DPH contracts and reviewed the medication records of 147 clients. Based on our review, we found 43 procedural medication administration errors ranging from the nonreporting of a medication occurrence to the inaccurate documentation of medical records.

3. **MAP Program Training and Participation Requirements Are Less Comprehensive Than Similar Certification Programs in Other States:** As part of our audit, we assessed the adequacy of program participation and training criteria in MAP with similar programs in other states. After conducting a survey we found that MAP program training and participation requirements are less comprehensive than those of similar programs in other states. Specifically, Massachusetts was the only state surveyed which directly authorized unlicensed individuals to administer medications. In addition, some states with similar programs have much stricter training and continuing education requirements.

**OTHER MATTERS**

**APPENDICES**

A. Ad Hoc Panel Recommendations for Medication Administration Program

B. Recommendations and Depositions by the House Post Audit and Oversight Bureau

C. Audit Sites Visited
INTRODUCTION

Background

On November 18, 1988, the Office of the State Auditor issued an audit report (No. 87-1080-3) entitled, “Report on the Activities of the Department of Mental Health’s Licensing Division.” This report disclosed that unlicensed and untrained individuals were administering medications to consumers in Department of Mental Health (DMH) and Department of Mental Retardation (DMR) community-based programs, contrary to Chapter 94C of the Massachusetts General Laws, which authorizes only licensed individuals (e.g., medical doctors and nurses) to administer medications. However, Chapter 94C, Section 7g of the General Laws allows the Commissioner of the Department of Public Health (DPH) to authorize other individuals to administer medication by stating, in part, “The commissioner may by regulation authorize the registration for a specific activity or activities requiring registration under this section of such persons as he determines to be qualified for such registration.”

In August 1993, DPH promulgated 105 Code of Massachusetts Regulations (CMR) 700.003 (F), which authorizes certain staff members to administer medication to certain clients in community programs by stating, in part:

Employees of community programs may administer or assist in the administration of prescription medications to non-self-medicating persons, provided that the community program is registered, the employee is trained and the program meets the storage, labeling, administration and documentation requirements of the regulations . . . no unlicensed staff person may administer or assist in the administration of prescription medications without successfully completing a training program which meets the specifications for a training curriculum and examination process established jointly by the Department of Public Health, and the Department of Mental Health and/or the Department of Mental Retardation.

Both DMR and DMH promulgated companion regulations for the administration of prescription medication to non-self-medicating individuals in their community-based programs. DMR promulgated 115 CMR 6.06 (5), which states, in part, “for non-self-medicating individuals receiving services in the community, prescription medication may be administered by community program staff who have successfully completed the Department approved Medication Administration Training Program and have
been certified by the Department for such activities.” These regulations would permit administration of medications by certified staff in community programs. The DMH regulation, 104 CMR 28.06 (8), states in part, “Prescription medication shall be administered . . . by other community program staff who have successfully completed the Department-approved medication administration training program and have been certified by the Department for such activities.”

As a result of these regulatory changes, DPH, in collaboration with DMH and DMR, established the Medication Administration Program (MAP). This program, which provides for oversight of the administration of medications in community-based residences and allows unlicensed but certified direct care staff to administer prescription drugs to non-self-medicating DMR and DMH individuals in their community-based residences. Since the program’s inception through the end of our audit period, the program had graduated over 31,308 direct care workers. As of the end of our audit period, there were 11,547 non-self-medicating DMH and DMR individuals in 2,441 sites involving 250 service providers.

In order to successfully complete the MAP training program and become certified, program participants must receive 12 hours of training and four hours of written and practice testing for medication administration in various areas, including:

- Understanding medication forms
- Transcribing a new medication order
- Reading and understanding medication information sheets
- Writing progress notes from patient doctors’ visits
- Training in other general areas, such as the safe storage and administration of medication
- Reading and understanding prescription nomenclature
- Understanding dosage and time specifications
- Obtaining information on drug side effects
- Reporting of medication occurrences
- Understanding medication emergency procedures
Some other key provisions of the DPH regulations that established MAP are that: (1) all community programs participating in MAP must be registered with DPH, (2) persons administering medication in MAP become recertified every two years, (3) a Medication Occurrence Reporting (MOR) system be used for the reporting and documenting of medication occurrences by contracted service providers, and (4) DPH be permitted to inspect program and client records.

In addition to establishing MAP, in 1994 DPH convened a MAP Advisory Group. The purpose of this group was to have community stakeholder representation in MAP, providing input on issues and as a forum for recommending changes in program policies and amendments to existing regulations. The group was composed of members from the state Legislature; regulatory agencies such as the Board of Registration in Nursing (BRN); representatives from DPH, DMH, and DMR; service providers operating community programs (i.e., residences and group homes); and other public interest groups and associations, such as the Massachusetts Nurses Association (MNA). DPH initiates group meetings and invites members to attend.

The group was instrumental in the revision of MOR, including the adoption of a more standardized method for reporting and documenting medication occurrences, which became effective December 1, 1996. The group also helped develop DPH’s hotline reporting via the telephone for medication occurrences that resulted in medical intervention, illness, injury, or death at contracted service providers. It also helped to develop a DPH MAP Policy Manual, issued September 30, 1998, which providers are required to keep at each program site. This policy manual, in addition to compiling prior policies, addresses various MAP issues, such as transcribing health care providers’ medication orders, monitoring vital signs, exhausting the current supply of medication, monitoring blood glucose, administering medications that require injection, and distributing over-the-counter medications.

In November 1996, DPH convened a panel known as the Ad Hoc Panel on Development of Evaluation Measures for the Medication Administration Program to develop evaluation measures that would provide both direct and indirect indicators for the measurement of MAP’s effectiveness. The panel
was composed of seven professionals, including physicians, pharmacists, nurses, and researchers. In July 1997, the Ad Hoc Panel presented 22 recommendations for improvement to the commissioners of DPH, DMH, and DMR (see Appendix A). As of the end of our audit fieldwork, 12 of these recommendations had been implemented. Additionally, DPH officials told us that they have taken measures to address the concerns raised in the remaining 10 recommendations. As a result of these recommendations, in December 1997 DPH, in cooperation with DMR and DMH, developed a MAP clinical review process. This process authorizes DPH to assess contracted service providers’ clinical and medication administration practices, including safety for consumers, program effectiveness, and compliance with regulations (105 CMR 700.003) promulgated by DPH.

When MAP was initially implemented, the training and testing phases of the certification program were developed cooperatively by DPH, DMR, and DMH and administered in-house cooperatively by DMR and DMH. The curriculum consisted of 12 hours that included both practical and textbook training. However, in 1998, the MAP Advisory Group expressed concerns over the appropriateness of the MAP curriculum and the lack of independence with the test given as each state agency certified its own staff.

As a result, the Advisory Group recommended that an independent consultant be hired to develop a new curriculum and that an independent agency administer the test. Subsequently, on May 24, 1999, DPH increased an existing contract that it had with the Mount Auburn Hospital in Cambridge for Prevention Support Services by $58,000, to include $10,000 for a revision of the MAP curriculum. This new curriculum, which was implemented in September 1999, consists of 12 hours of training and must continue to be administered by professional trainers, such as registered nurses and pharmacists. During fiscal year 1999, DMH and DMR also awarded a $20,000 contract to the Waltham Committee Inc., to develop supplemental training videos for direct care staff administering medication to consumers that are deaf or hard of hearing. Additionally, on March 3, 1999, DMR awarded the American Red Cross of Massachusetts Bay (ARC) a five-year contract that had a maximum obligation of $3,521,241 to
administer centralized testing to MAP participants. The ARC test consists of a 60 minute written examination consisting of 50 multiple choice questions and a practical skills test. The multiple choice knowledge test is based on the following areas:

- Basic concepts of medications
- Storage and control of medications
- Administration of medications
- Observing and reporting

The skill test involves the following:

- The accurate transcription of a physician’s medication order of a countable substance onto an individual’s medication and treatment sheet
- Appropriate administration of medications (simulation)
- Accurate documentation of the administration

As part of its contract, ARC maintains a database for the tracking and scheduling of all certified staff for recertification as well as the DMR and DMH trainers. ARC sends reminder letters and applications to staff 90 days prior to the expiration date of a certificate and schedules a time and place for the test. Once the employees successfully pass the written and skill tests, they are certified by DMH and/or DMR for a period of two years and are qualified to administer medications. For recertification, individuals are only required to take and pass the practical skills portion of the test.

Although DPH, DMH, and DMR have taken measures to improve MAP, a few groups, most notably the MNA, have been critical of MAP. Specifically, according to information provided to us by MNA officials, MAP-trained individuals are providing a lower quality of care to consumers than could be provided by professional nursing staff. MNA officials indicated that for a variety of reasons, MAP’s training and testing costs are more expensive than using licensed nursing care to provide these services. However, MNA officials did not provide us with any documentation to substantiate these assertions.
Additionally, in June 1998, the state’s House Post Audit and Oversight Bureau (HPAOB) conducted a review entitled “Review: Medication Administration Program: DMR, DMH” of MAP for 1996 and 1997. Based on this review, the following seven concerns were identified:

- A system for professional oversight is needed and should recognize that the needs of clients from each agency are different.

- The limited ability to place licensed personnel on all sites on an ongoing and regular basis has significant cost implications. The appropriateness of administration by unlicensed personnel has been hotly contested especially in the context of certain settings. In particular, issues relating to administration to individuals with “G tubes,” injectibles and complex antipsychotics have been major sources of conflict between agencies, recipients, and licensed personnel.

- In all likelihood the number of errors and occurrences in the administration of medication was understated. Issues such as staff turnover and confusion about the types of incidents and what constituted an occurrence contributed to the underreporting of medication errors.

- As a general statement there was little incentive to report medical occurrences, especially “minor” occurrences. HPAOB found a system that had limited ability to detect underreporting of occurrences or medication errors.

- Miscommunication was a significant issue that affected the level of problems with MAP. Instances occurred in which prescribing physicians did not communicate dosage changes to either pharmacists or staff.

- The personnel assigned responsibility for the administration of medication to clients may be inadequate given the low salaries and continuing problems with staff turnover.

- The legal and liability issues relating to the program may be understated. Simply placing nurses in positions of oversight of unlicensed personnel may result in direct liability for the particular nurse who performs oversight in cases where serious errors occur.

In its conclusion, HPAOB stated the following in its report:

The Bureau remains concerned about the long-term prospects for the MAP program. While no group is satisfied with the current status, it is clear to the Bureau that the proposal before the Legislature represents a significant improvement. The oversight, training and turnover issues that confront the staff of this program are significant and long term. The Bureau believes however, that the current Commissioners and members of the Health Care Committee have demonstrated the kind of leadership and commitment necessary to make the program successful. The fiscal impacts of the program remain in doubt. The Bureau believes that it and other interested parties must work cooperatively to ensure that the issues raised in this report continue to be addressed.

Included in HPAOB’s report were the following recommendations:

- DPH should establish a Quality Review Team, including MNA and the Professional Nurses Association, to ensure the integrity and the effective operation of the MAP program. This group
should meet regularly with the affected agencies and commissioners to discuss planning and implementation issues.

- DMH and DMR should agree to spot checks and inspections of the MAP program’s operation by the quality review team and report findings to HPAOB and DPH.

- DMH and DMR should agree to provide monthly progress reports on the MAP program to HPAOB.

In addition, HPAOB recommended that a particular case [the “Conrad Simon case”] be reinvestigated by the Disabled Persons Protection Commission to re-evaluate the inconsistency in information reported. The disposition of these recommendations appears in Appendix B.

**Audit Scope, Objectives, and Methodology**

The scope of our audit included an examination of certain activities of DPH, DMH, and DMR relative to their administration of MAP. Our audit was conducted in accordance with applicable generally accepted government auditing standards for performance audits promulgated by the Comptroller General of the United States and included such audit procedures and tests as we considered necessary.

The overall objective of our audit examination was to determine whether the administration of MAP was meeting the intent of Chapter 94C of the General Laws (the Controlled Substances Act) by ensuring that medications are administered to citizens in a safe and responsible manner. Our specific objectives were to:

- Meet with DPH, DMH, and DMR officials to obtain an understanding of how MAP is being administered by each of these agencies.

- Determine the current status of MAP as a result of the recommendations and improvements made by other agencies and legislative bodies.

- Perform audit testing at various DMH and DMR community residences in order to assess the effectiveness and efficiency of various MAP program activities.

- Assess the adequacy of the control systems established by DPH for measuring, reporting, and monitoring the program’s effectiveness.

- Review the dispensing of medication at selected community-based residences to determine whether it is done in a manner consistent with applicable laws and regulations.
• Solicit and analyze information regarding similar programs in other states to compare criteria and prerequisites.

• Make recommendations on how to improve the administration of this program, if applicable.

To achieve our audit objectives, we held discussions with officials from DPH, DMH, DMR; the BRN; MNA; and contracted service providers of DMR and DMH. We also reviewed pertinent laws, regulations, policies and procedures, contractual agreements, and medication records maintained by DPH, DMH, and DMR relative to their administration of MAP. In addition, we conducted site visits at 48 community residences and 12 provider administrative offices. During our site visits, we held discussions with officials from each service provider and reviewed each provider’s policies and procedures. We also reviewed the medication records, medication logs, and pharmacy records of 147 clients residing at these sites (see Appendix C for a listing of site visits). The purpose of our site visits was to assess how the medication administration process was being conducted in these residences and the extent to which any medication problems were occurring. Additionally, we reviewed the clinical review process and the MOR process for effectiveness and compliance with applicable policies. We also solicited and analyzed information on medication administration from other states that had similar programs to compare criteria and prerequisites.

Our special-scope audit reviewed certain medication administration activities being conducted by DMH, DMR, DPH, and a selected number of contracted human service providers. Our audit did not include an assessment of the adequacy of other program services being provided at the program sites that we visited.

AUDIT RESULTS

1. Deficiencies Found in MAP Medication Occurrence Reporting Process

We noted several deficiencies in the Medication Occurrence Reporting (MOR) process utilized by the Department of Mental Health (DMH) and the Department of Mental Retardation (DMR), including: (1) contracted service providers in 40%-71% of the records we reviewed did not report in writing all
incidences of medication administration errors to their state purchasing agencies within the timeframe established by the Medication Administration Program (MAP) policies, (2) contracted service providers in 57%-68% of the records we reviewed did not report medication administration errors that resulted in medical intervention (e.g., hospitalization) within 24 hours as required by MAP policies, and (3) MORs were not effectively utilized to ensure that individuals who made medication errors were identified and properly trained to prevent future medication errors.

Contracted service providers are required by 105 Code of Massachusetts Regulations (CMR) 700.003 (F)(1)(f), promulgated by the Department of Public Health (DPH), to document each MOR in the client’s records. These regulations also require service providers to promptly report to the DMH and DMR any medication error or violation of DPH regulations “which staff has reason to believe created a risk of harm to the client. Such form shall be provided, upon request, to the Department of Public Health.”

When MAP was first established in 1994, DMH and DMR each had its own MOR process in which service providers used unique reporting forms to report any incidences of medication errors. Effective December 1, 1996, under advice from the MAP Advisory Group, a standardized MOR was developed for the purpose of recording and reporting medical errors. This standardized MOR form lists program location, client name, date of occurrence, type of occurrence, medication involved, consultant contacted, whether medical intervention or illness occurred, whether the occurrence was followed by injury or death, and whether DPH was notified within 24 hours. The form also provides space for supervisory review/follow up of the occurrence; contributing factors, if any; and the signature of the staff person’s supervisor.

Under this process, when any of these five conditions--right person, right medication, right dose, right time, and right route--are violated in the administration of medications, a MOR must be prepared by the contracted service provider and sent to either DMH or DMR for review and input into an agency database. At the time of each occurrence, MAP-certified staff are required to call a consultant (either a registered nurse, registered pharmacist, or licensed health care practitioner) for advice.
According to the MAP Policy Manual, when these occurrences are followed by medical intervention (i.e., hospitalization), or if illness, injury, or death occurs, DPH must be informed within 24 hours. These occurrences are commonly referred to as hotline MORs. Moreover, the Manual requires that copies of all MORs are forwarded to DMH/DMR MAP coordinators within seven days of the occurrence, whereas the original forms must remain at the program site. Also, DMH and DMR are required to forward statistical reports on medication occurrences and copies of all MORs to DPH on a monthly basis. These statistical reports of MOR activity are used by the departments to generate the monthly progress reports (quarterly as of April 2000) provided to the House Post Audit and Oversight Bureau (HPAOB).

Our review of the records maintained by DPH, DMH, and DMR relative to MORs filed by service providers during the period of our audit identified the following deficiencies:

a. **Noncompliance with DPH Regulations Relative to the Reporting of MORs:** As previously mentioned, according to the MAP Policy Manual, contracted service providers are required to forward copies of MORs to DMH and DMR within seven days of the date of the incident. However, according to information we obtained from DPH, some contracted service providers did not comply with this MAP Policy. The following is a summary of MORs reported by service providers to DMH and DMR during this period:

<table>
<thead>
<tr>
<th>State Agency</th>
<th>Total MORs Reported</th>
<th>Number Reported within Seven Days</th>
<th>Number Reported after Seven Days</th>
<th>Percentage Reported Late</th>
</tr>
</thead>
<tbody>
<tr>
<td>DMH</td>
<td>3,701</td>
<td>2,239</td>
<td>1,462</td>
<td>40%</td>
</tr>
<tr>
<td>DMR</td>
<td>6,541</td>
<td>1,876</td>
<td>4,665</td>
<td>71%</td>
</tr>
</tbody>
</table>

As can be seen from the table above, during this two-year period, 40%-71% of the MORs were not reported to their respective agencies by service providers within the seven-day period. In fact, DPH,
DMR, and DMH did not maintain an analysis of how late MORs are filed. Rather, these agencies only identify whether or not an MOR is filed late. Therefore, the actual number of days these MORs were filed past the seven-day requirement could not be determined.

b. **Hotline MORs Not Reported in a Timely and Accurate Manner:** As previously mentioned, all hotline MORs must be reported to DPH within 24 hours of the incident. Also, effective March 1, 2000, DMH instituted an “Area MAP Coordinator Hotline MOR Follow up” form that would document, in summary form, the follow up conducted on hotline MORs by the respective MAP coordinator and determine whether further action is indicated. DMR instituted a similar form for MAP coordinators called the “Reporting Hotline Form,” effective March 1, 2000, for the purpose of ensuring that all hotline MORs are properly reported to DPH.

During our audit, we reviewed the documentation maintained by DMR and DMH relative to hotline MORs reported and found the following deficiencies:

- **During the period July 1, 1998 to December 31, 2000,** service providers reported 55 hotline MORs to DMH, of which we randomly selected 14 to review. We found that eight of the 14 (57%) had not been reported to DPH within the required 24-hour period. The number of days after the medication error occurred to when it was reported ranged from one to 45 days. Six of these eight hotlines represented calls for clients who were sent to hospital emergency rooms, hospitalized, or both. Moreover, one of the 14 was never reported to DPH by the service provider.

- **During the period July 1, 1998 to December 31, 2000,** service providers reported 98 hotline MORs to DMR, of which we randomly tested 19 for our review. We found that 13 of the 19 (68%) had not been reported to DPH within the required 24-hour period. The number of days from the date of the medication error to the date it was reported ranged from one to four days. Ten of these 13 hotlines represented calls for clients who were sent to hospital emergency rooms, hospitalized, or both.

- **We reviewed 42 hotline occurrences recorded on the DPH log from January 1, 1998 to October 1, 1998.** Based on our review, we found that service providers did not distinguish between critical (hotline) and non-critical MORs. Specifically, there were 12 MORs that were submitted by service providers as non-critical but were later reclassified as being critical when reviewed by the DMH/DMR officials.
DMH and DMR officials could not explain why the service providers were not reporting MORs as required. However, both DMH and DMR officials told us that they now conduct final reviews of all MORs to ensure that they are properly classified and reported.

c. Disincentive for Service Providers to Report MOR: There may be an inherent disincentive for service providers to report all incidents of errors in medication administration, since this could potentially effect a state purchasing agency’s desire to award contracts to an organization. A report issued by HPAOB raises similar concerns by stating that “the number of errors was understated” and that “as a general statement there was little incentive to report [medical occurrences], especially to report minor occurrences.” Despite the concerns raised by the HPAOB in its report, during our site visits, we found only one instance in which a service provider did not report a medication error on a MOR. However, we found that on a statistical basis all medication errors may not be reported. According to a study published by the American Medical Association, the typical medication error rate in medical facilities is approximately 3%. During our audit, we analyzed the MOR information maintained by DMH and DMR for our audit period, which is summarized as follows:
Summary of MOR Reporting Program Sites
Fiscal Years 1998 and 1999 (Combined)

<table>
<thead>
<tr>
<th>Total Program Sites</th>
<th>Number That Have Filed MORs</th>
<th>Number That Did Not File MORs</th>
<th>Percentage of Total That Did Not File MORs</th>
</tr>
</thead>
<tbody>
<tr>
<td>DMH</td>
<td>584</td>
<td>424</td>
<td>160</td>
</tr>
<tr>
<td>DMR</td>
<td>1,258</td>
<td>729</td>
<td>529</td>
</tr>
</tbody>
</table>

Summary of MOR Reporting by Service Provider
Fiscal Years 1998 and 1999 (Combined)

<table>
<thead>
<tr>
<th>Total Service Providers</th>
<th>Number That Have Filed MORs</th>
<th>Number That Did Not File MORs</th>
<th>Percentage of Total That Did Not File MORs</th>
</tr>
</thead>
<tbody>
<tr>
<td>DMH</td>
<td>74</td>
<td>68</td>
<td>6</td>
</tr>
<tr>
<td>DMR</td>
<td>142</td>
<td>142</td>
<td>6</td>
</tr>
</tbody>
</table>

As can be seen from the table, a significant percentage (8% of DMH’s contracted service providers and 27% of program sites) have never filed MORs. Similarly, although 100% of DMR’s service providers have filed MORs, a significant percentage, 42% of all the program sites operated by DMR’s contracted service providers, have never filed MORs.

d. MORs Were Not Effectively Utilized to Ensure That Individuals Who Make Medication Errors Are Properly Trained: During our audit, we noted that the MOR reporting process was not being effectively used by DPH, DMH, or DMR to ensure that individuals who make medication administration errors are properly trained to reduce the occurrences of future errors. Specifically, DPH’s policy states that direct care staff members who commit medication errors do not have to declare their names on the MOR. According to agency officials, the MOR is used as a quality assurance mechanism to prevent errors, not to count them. Officials at DMR and DMH informed us that providers are responsible for the administration of medication by their direct care staff and for keeping track of those individuals who make errors. These officials also stated that their agencies do not have procedures for monitoring any
training that providers give to their direct care staff and that they therefore cannot determine whether individuals who commit medication errors receive any additional training. By not requiring service providers to identify who was responsible for the medication errors, DPH, DMH, and DMR cannot effectively monitor staff who may need to be retrained to ensure that they properly administer medications.

**Recommendation:** DPH, in conjunction with DMR and DMH, should take measures to improve the integrity of the MOR process. At a minimum, these measures should include developing policies and procedures to ensure that all MORs, including hotline MORs, are reported in an accurate and timely manner. DPH may want to consider imposing sanctions on those service providers who do not report MORs as required. Additionally, DPH should ensure that individuals performing medication administration errors receive additional training and supervision.

**Auditee Response:** In response to this draft audit result, DPH, DMH, and DMR officials stated, in part:

The analysis of medication occurrence timeliness is problematic because it appears not to take into consideration; (i) the time interval between the dates of occurrences and their discovery; (ii) the degree of lateness of reports; and (iii) business days instead of calendar days. More importantly, we are concerned that the analysis isolates the timeline policy from its context and places undue emphasis on this aspect of reporting, which is not even mentioned in the regulations. We believe that the report fails to give due consideration to the primary goals of the Medication Occurrence Reporting (MOR) system, which are to create a non-punitive environment conducive to the reporting of complete and accurate information and to utilize MOR data for retrospective analysis.

**Auditor’s Reply:** To the contrary, our analysis of medication occurrences timeliness was based on the information provided to us by DPH, DMH, and DMR during our audit and is not in any way problematic. Since DPH, DMR, or DMH did not maintain information regarding MORs being filed late, the time intervals between the dates of occurrences and their discovery and the degree of lateness could not be demonstrated. Moreover, the department’s assertion that our MOR reporting analysis, not including business versus calendar days, is irrelevant. The fact is DMH and DMR’s own records indicate that 40% and 71%, respectively, of the MOR reports that had been filed with these agencies during
between January 1, 1998 and December 31, 1999 were filed late. For the MOR process to perform at an optimal level, DPH, DMH, and DMR should take measures to ensure that all MORs are filed in a timely manner in accordance with MAP policies.

While we acknowledge that the requirements of the specific timeline for filing MORs are not mentioned in the regulations, they are specified in MAP policies that were adopted by the departments and therefore should be adhered to. The MAP Advisory Group, the Ad Hoc Panel on Development of Evaluation Measures for the Medication Administration Program, and the HPAOB had concerns regarding the reporting of medication errors, which also led to the current policies being adopted.

Furthermore, we disagree with the departments’ assertion that our report does not give due consideration to the primary goals of the MOR system. Clearly, all aspects of the MOR process—the timeliness of reporting, the identification of staff members that make medication errors, and the accuracy of reporting and the independence of the reporting process—contribute to the overall quality of client care and were considered during the conduct of our audit field work.

2. **The MAP Monitoring Process Needed Improvements**

DPH is authorized to perform clinical reviews of all registered community residences in the Commonwealth. In this regard, 105 CMR 700.003(F)(1)(d), promulgated by DPH, states, in part:

The Department of Public Health shall be permitted by the program to inspect program and clients’ records pertaining to the use and administration of prescription medications and is permitted announced or unannounced on-site visits or inspections of common areas and such other inspections as the Department of Public Health is authorized to make in order to monitor the program’s compliance with 105 CMR 700.000.

The MAP clinical review process was developed by DPH in cooperation with DMR and DMH, and was implemented in December 1997. According to DPH officials, the purpose of these reviews is to provide independent oversight relative to the administration of medication at contracted service providers, as recommended by the Ad Hoc Panel in July 1997. These officials stated that clinical reviews allow DMR and DMH to address identified areas of concern and revise or develop policies and procedures, where necessary, to improve programs. According to DPH officials, a clinical review takes two to three
days to complete and includes a review at the contracted service provider’s main office and a sample of its individual program sites. During a clinical review, the DPH reviewer, who is typically a registered nurse, utilizes a checklist that details the criteria with which programs must comply. DPH officials stated that the clinical reviewer selects a geographical region within the state and randomly selects programs within this region that have not been previously reviewed to visit. In the event of a complaint about a particular program, it is given priority and reviewed immediately. DPH Policies No. 15-1 and No. 15-2 provide a description of the steps involved in the department’s clinical review process. The steps contained in DPH Policy No. 15-2 are summarized below:

- Service providers are notified by DPH of the date and time scheduled for a clinical review.
- The clinical review process is conducted at both the service provider’s administrative office and selected sites.
- Following the clinical review, findings are reviewed with the service provider.
- A copy of the clinical review findings is subsequently forwarded by DPH to the service provider and DMH or DMR.
- The service provider is required to submit a plan of correction within 10 days to DPH and the appropriate licensing/certifying agency (i.e., DMH or DMR).
- DMH or DMR, in consultation with DPH, conducts follow up on the plan of correction.

The Checklist for Program Providers covered during a clinical review are summarized as follows:

- Verification – Provider has registered all sites, maintained current files on all sites, and maintained a current listing of agencies that supply relief staff.
- Certification – Provider maintains file of all staff MAP certifications, recertifications, and specialized training with documentation of current status, maintains same information for relief staff, and maintains documentation of staff training and competency for vital signs monitoring.
- Education – provider identifies and trains staff responsible for off-site medication administration, offers ongoing medication education to staff members, and maintains current list of staff members attending ongoing medication administration education.
- Medication Emergencies – Provider maintains policies and procedures to be followed for medical emergencies.
- Medication Occurrences – Provider utilizes the standard MOR form when required, reports “Hot Line” calls to DPH within the required 24-hour period, reports MORs to DMR/DMH within the required seven-day period, and maintains copies of MORs on site.

- Preparation of Medication for Administration – Policies and procedures for Leave of Absences (LOA) must be implemented when preparing medications for LOA’s, properly labeled containers are used when a client receives medication in two or more locations.

Checklist for Program Sites covered during a clinical review is summarized as follows:

- Staff Certification – Site maintains file of all staff MAP certifications, recertifications, and specialized training with documentation of current status and expiration dates; maintains the same information for relief staff; maintains documentation of staff training and competency for vital signs monitoring; and maintains a list of CPR certifications with expiration dates.

- Staffing – Only MAP-certified staff may administer medication. If medications are administered by G-tube or J-tube, staff must have received additional DPH training.

- Medication Emergencies – Site has current list of emergency numbers, MAP consultants, and poison control center clearly posted and client emergency information form is complete, accurate, and current.

- Reference Materials – Site maintains written specific information for medication administration and provides certified staff access to pertinent materials regarding medication administration.

- Medication Occurrences – Site completes an MOR when required, reports “hot line” calls to DPH within the required 24-hour period, reports MORs to DMR/DMH within the required seven-day period, and maintains complete MORs at site.

- Vital Signs – Site consults with health care providers to determine whether vital sign monitoring is necessary, obtains written consent from health care provider, ensures that only licensed or certified staff can monitor vital signs, ensures that vital sign monitoring is properly recorded, notifies health care provider if vital signs are not within ordered parameters, and documents such notification to health care provider.

- Documentation – Site has current copy of policies and procedures, client records contain no evidence of crossing out or marking over; the word “error” is written if an error is made in the client record; information regarding client medication is documented in the record; forms are organized and clear; allergies are listed; all medications given are listed; if medication is not given when required, documentation indicating the reason and notification to health care provider for medication not given; PRN [“as needed”] orders are documented; and site maintains accurate and current seizure records.

- Physician Orders/Transcription – Telephone change orders are received only from licensed practitioners, telephone change orders are signed by health care provider within 72 hours, orders are up-to-date, changes in medication orders are handled as new orders, transcriptions are done accurately and correctly, forms and medication labels are consistent, and PRN orders have specific target symptoms and instructions for use.
• Medication Administration – Over-the-counter medications are administered in accordance with guidelines, medications administered by G-tube/J-tube are administered by certified staff who have completed specialized training, site obtains specific written parameters for consumers receiving insulin, sites follow instructions noted in ISP/PSTP when changing mode of medication, medications are prepared in accordance with leave of absence policy, and corrective action is taken in a timely manner when medication emergencies arise.

The clinical review checklist also includes sections for comments and timelines for the correction of any deficiencies identified during the review. According to DPH officials, at the end of a clinical review, the reviewer meets with program staff to discuss any deficiencies identified, proposed recommendations, and correction timelines. Subsequently, DPH forwards a written copy of the results of the clinical review to the service provider and the applicable oversight agencies (i.e., DMR or DMH). The service provider is required to submit a plan of corrective action within 10 days to DPH and the appropriate oversight agency. According to DPH officials, the oversight agencies, in consultation with DPH, are responsible for follow up on the deficiencies with service providers to ensure they are corrected.

During our audit, we reviewed the documentation maintained by DPH relative to its clinical review process and noted several deficiencies. First, DPH officials informed us that the clinical review is primarily an educational process. The reviewer conducts an overall review of the system through interviews with staff and a review of the provider’s records but does not actually observe staff activities at the provider’s place of business or the provider’s program sites. Further, DPH does not have an established schedule or plan that identifies when to visit each provider’s site. Also, although the MAP clinical review form has specific areas to be reviewed, it does not include procedures as to how the reviews should be carried out, what types of records/files are to be examined, and the personnel that are to be interviewed. Furthermore, from January 1998 through the end of our audit period, DPH had only one individual assigned to conduct these reviews at approximately 250 community-based programs involving 2,441 program sites. Since, according to DPH officials, it takes two to three days to perform these reviews, at most only between 80 and 125 reviews of the 250 potential programs can be conducted
annually. However, we found that, of the 2,441 program sites, 2303 sites operated by 207 service providers had never been reviewed.

Our analysis of all the clinical reviews performed from its inception in December 1997 through December 31, 1999 revealed that 138 sites (6%) operated by 43 service providers (17%) had undergone clinical reviews. The reviewer identified 1,936 deficiencies in the following areas:

<table>
<thead>
<tr>
<th>Type of Deficiency - Providers</th>
<th>Total Deficiencies</th>
<th>Percentage of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verification</td>
<td>23</td>
<td>1.2</td>
</tr>
<tr>
<td>Certification</td>
<td>53</td>
<td>2.7</td>
</tr>
<tr>
<td>Education</td>
<td>50</td>
<td>2.6</td>
</tr>
<tr>
<td>Medication emergencies</td>
<td>18</td>
<td>1.0</td>
</tr>
<tr>
<td>Medication occurrences</td>
<td>39</td>
<td>2.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of Deficiency – Program Sites</th>
<th>Total Deficiencies</th>
<th>Percentage of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation of medication for administration</td>
<td>21</td>
<td>1.1</td>
</tr>
<tr>
<td>Certification</td>
<td>231</td>
<td>11.9</td>
</tr>
<tr>
<td>Staffing</td>
<td>52</td>
<td>2.7</td>
</tr>
<tr>
<td>Medication emergencies</td>
<td>103</td>
<td>5.3</td>
</tr>
<tr>
<td>Reference materials</td>
<td>66</td>
<td>3.4</td>
</tr>
<tr>
<td>Medication occurrences</td>
<td>118</td>
<td>6.1</td>
</tr>
<tr>
<td>Vital signs</td>
<td>316</td>
<td>16.3</td>
</tr>
<tr>
<td>Documentation</td>
<td>486</td>
<td>25.1</td>
</tr>
<tr>
<td>Physicians orders/transcriptions</td>
<td>269</td>
<td>13.9</td>
</tr>
<tr>
<td>Medication administration</td>
<td>91</td>
<td>4.7</td>
</tr>
<tr>
<td>Totals</td>
<td>1,936</td>
<td>100%</td>
</tr>
</tbody>
</table>

Given the significant number of medication deficiencies (approximately 14 per site) being identified during each clinical review, it is important that DPH ensure that clinical reviews are conducted at all program sites on a regular basis.

As previously mentioned, although DPH conducts these clinical reviews, DPH officials informed us that DMH and DMR are responsible for following up on any deficiencies DPH may identify during these reviews. However, our review of the follow up activities conducted by DMH and DMR identified that during the period of our audit, neither agency had any formal written polices and procedures on how to follow up on DPH’s clinical reviews. DMH and DMR officials told us that, although there are no written
policies and procedures, their respective agencies have established a process to follow up on any deficiencies found during clinical reviews to assess whether the deficiencies had been corrected.

Specifically, in December 1997, DMR and DMH developed what they call a Technical Assistance Tool (TAT), which is a checklist that includes 17 areas of review including all the elements of DPH’s clinical review. DMR and DMH officials told us that their agencies use this tool as a way to follow up on deficiencies that are identified during DPH’s clinical reviews.

However, our review of the TAT process at both DMR and DMH revealed several deficiencies. First, TAT does not require corrective action plans to be implemented by providers to correct any deficiencies noted. According to DMH and DMR officials, TAT is primarily used for monitoring and training, rather than a policing tool. Therefore, the results are not formally reported but are verbally communicated to service providers. Also, we found that DMR and DMH used the TAT review process differently. At DMR, the Director of Health Services uses TAT discriminately, such as when a MOR is reported or when DMR receives a complaint about a provider. In these situations, the Director would ask the MAP Coordinator to conduct a TAT review at the program site in question. However, the Director told us TAT does not routinely follow up on all clinical reviews. In contrast, DMH officials told us that it routinely uses TAT to conduct reviews at all of its service providers.

During our audit at DMR, we selected three of DMR’s vendors that were operating nine program sites that had a clinical review done by DPH between July 1, 1999 and December 31, 2000. During the clinical review conducted at these vendors, DPH identified 124 deficiencies, including medication errors and medical interventions not being reported, inadequate written policies and procedures in place to address staff training and monitoring of vital signs, inadequate documentation of clients needs relative to allergies medication treatment, and unsatisfactory controls over training certifications and the recertifications of MAP staff. DMR officials were unable to provide us with documentation relative to any follow up measures conducted by DMR that it had taken relative to the deficiencies identified during these clinical reviews.
During our audit at DMH, we identified three vendors who were operating seven program sites that had a clinical review done by DPH between July 1, 1998 and December 31, 2000. During the clinical reviews conducted at these programs, DPH identified 78 deficiencies, including programs at DPH not being registered, inadequate policies and procedures in place for vital signs monitoring, improper documenting of clients’ needs relative to medication treatment, and the improper administration of telephone medication orders. When DMH officials were asked to provide documentation relative to any follow up measures it had taken on the deficiencies identified in these reviews, DMH officials provided us with the following:

- At five of these program sites with 44 deficiencies, DMH could not provide us with specific documentation indicating that any follow up measures had been taken.

- At the other two vendor sites where DPH identified 34 deficiencies, DMH provided us with copies of two TAT reviews that were conducted at these vendors subsequent to DPH’s clinical review. However, neither of these TAT reviews indicated that any follow up review work was conducted on the 34 deficiencies DPH had identified at these two vendors during its clinical reviews.

In addition to TAT, both DMH and DMR told us that, as part of the MAP Improvement Plan, both agencies had incorporated their Licensing (DMH) and Survey Certification (DMR) Divisions into MAP requirements that must be reviewed while conducting these inspections. A review of DMH’s licensing inspection forms indicated that some MAP criteria were included in these evaluation forms. For example, the licensing criteria included the following: staff administering medication have a current MAP certification, all medication administered in the program is prescribed by a licensed physician, and medication prescriptions should not be kept at the program site. DMH presented us with a licensing review completed at one of its vendor’s program sites on October 26, 1999 as evidence of follow up for a DPH clinical review conducted by DPH at this same program site on April 21, 1999. However, although the licensing inspection did contain some MAP compliance standards, the particular deficiencies cited by DPH in the clinical review were not referenced. In addition, programs are only subject to a licensing review every 18 months, and licensing is not used by DMH as a means to follow up on deficiencies noted during a DPH clinical review in an expeditious manner. Similarly, DMR conducts its survey
certifications every one or two years, and the documentation we reviewed relative to this certification process did not indicate any provisions to follow up on any deficiencies identified during DPH’s clinical reviews.

Because of these monitoring deficiencies, DMH, DMR, and DPH cannot be assured that the administration of medication in its programs is being conducted in a consistent and effective manner. In fact, during our audit, we reviewed a random sample of 147 client files at 48 program sites being operated by 12 service providers who were contracting with DMH and DMR. In these 147 client files, we found 43 procedural deficiencies relative to the administration of medication. These medication administration deficiencies ranged from improper medication log documentation to an example of a known medication error for which an MOR was not completed. In fact, out of 48 residences visited, 21 had one or more medication deficiencies. At two of the sites we visited, the medication Leave of Absence (LOA) policy, which covers the administration of medications when a client is away from the residence and will not be under the staff’s direct supervision, was not followed resulting in controlled drugs being issued to client caregivers without documentation or controls. Some program managers, supervisors, and certified staff were unaware of LOA policies. The following is a summary of the 43 medication deficiencies we identified during our audit:
Deficiency Description                      | No. of Deficiencies |
------------------------------------------|---------------------|
No double signature on drug control log   | 10                  |
Signature on medication log discrepancies | 10                  |
Prescription not available/wrong          | 7                   |
Crossouts on drug control log             | 3                   |
Improper storage                          | 2                   |
Leave of absence documentation            | 2                   |
Broken blister packs                       | 1                   |
Improper prepack of drugs                 | 1                   |
Late MAP registration                     | 1                   |
Medication occurrence not reported        | 1                   |
Medication records not locked             | 1                   |
Missing medication records                | 1                   |
Mixed controlled & uncontrolled drugs     | 1                   |
No central filing of MORs                 | 1                   |
Uncertified staff administering drugs     |                     |
Total                                     | 43                  |

**Recommendation:** DPH, in conjunction with DMH and DMR, should take measures to improve the MAP monitoring process. Such measures should include DPH’s establishing more specific formal written procedures relative to the selection of service providers to be reviewed, the type and number of documents that need to be examined during each review, and the staff members that need to be interviewed. DPH should also take measures to ensure that contracted service providers of DMH and DMR receive a clinical review on a regular basis. Also, DPH, in conjunction with DMH and DMR, should establish formal standard procedures on how to follow up on any deficiencies DPH identifies during its clinical reviews.

**Auditee’s Response:** DPH, DMH, and DMR officials stated, in part:

We take exception to the conclusion that, based on some limitations of the Clinical Review process, “the Commonwealth cannot be assured that consumers . . . are having all of their medications administered to them in a safe and consistent manner.” Administrative and procedural matters have no direct impact on individual outcomes and the effectiveness of oversight of MAP does not depend on any single oversight component, particularly one that is not specified by regulation. It was neither the design nor [the] intent of the Clinical Review process, given its limited resources (i.e., one clinical reviewer), to review all programs in the state on a regular basis. With respect to the issue of procedural documentation, the compliance criteria that define the Clinical Review process are fully documented.
Auditor’s Reply: We disagree with the notion that the administrative deficiencies we identified during our audit have no direct impact on the quality of MAP oversight and the quality of care being provided to consumers in DMH and DMR’s community-based programs. To the contrary, MAP monitoring activities, including clinical reviews, are crucial in ensuring that medication administration within community-based programs are being provided in a safe and consistent manner and that problems are identified and resolved expeditiously and effectively. Contrary to the departments’ response, during our audit DPH officials told us that the purpose of the clinical review is to provide independent oversight relative to the administration of medication at contracted service providers. These officials also stated that clinical reviews allow DMR and DMH to address identified areas of concern and revise or develop policies and procedures where necessary, to improve programs. Unless this is being done on a regular statewide basis, we question the effectiveness of the clinical review process.

Although the compliance criteria used by DPH during clinical reviews is documented, the other deficiencies we identified raises concerns over the effectiveness of this process. For example, we identified a lack of documentation relative to follow up on deficiencies, and a lack of review schedules or plans and procedures to be conducted during these reviews. Unless clinical reviews are being conducted using an established plan or schedule and detailed procedures, the departments can not be assured that providers are in compliance with all applicable laws, regulations, and MAP policies and procedures. Finally, due to the inconsistent use of TAT by DMR and DMH and the lack of documentation of follow up on the deficiencies noted in the clinical review process, it cannot be determined whether deficiencies are being corrected and program staff are receiving additional MAP training when necessary.
3. **MAP Program Training and Participation Requirements Appear to Be Less Comprehensive Than Similar Certification Programs in Other States**

As part of our audit, we assessed the adequacy of program participation and training criteria in MAP with similar programs in other states. After conducting a survey, we found that MAP program training and participation requirements appear to be less comprehensive than those of similar programs in other states. Specifically, Massachusetts was the only state surveyed which directly authorized unlicensed individuals to administer medications. In addition, some states with similar programs also have much stricter training and continuing education requirements.

During our audit, we attempted to compare the adequacy of program participation and training criteria in MAP with those of other similar programs. In order to do this, we conducted a survey of 27 states to obtain information relative to the administration of medication to individuals in residential (non hospital) settings in these states. Of the 18 states that responded, seven did not provide sufficient information to include in our analysis. As a result, data from 11 states--Rhode Island, Vermont, Maine, Kansas, Oregon, South Dakota, Maryland, Wyoming, Delaware, Georgia, and Missouri--were used in our analysis.

We found that four of the 11 states (Wyoming, Delaware, Georgia, and Missouri) did not allow unlicensed individuals to administer medication. The following table summarizes the information we obtained for the remaining seven states.
### Medication Administration by Unlicensed Individuals
**State Survey**
**As of June, 2000**

<table>
<thead>
<tr>
<th>States</th>
<th>Recognized by Statue</th>
<th>Type</th>
<th>Program Requirements</th>
<th>Reading Level Required</th>
<th># Course Hours Training</th>
<th>State Cert Required</th>
<th>Settings</th>
<th>Continued Education (CE) Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>MA</td>
<td>Yes</td>
<td>Direct authorization</td>
<td>None stated</td>
<td>Average for individual in US</td>
<td>12 hours</td>
<td>Yes</td>
<td>MH/IMR Group Homes</td>
<td>Skills Test every two years</td>
</tr>
<tr>
<td>RI</td>
<td>Yes</td>
<td>Nurse supervision</td>
<td>None stated</td>
<td>English reading/writing abilities</td>
<td>45 hours</td>
<td>Yes</td>
<td>Long Term Care (LTC)</td>
<td>None</td>
</tr>
<tr>
<td>VT</td>
<td>Yes</td>
<td>Nurse delegation</td>
<td>None stated</td>
<td>None stated</td>
<td>No specific training (individual by delegating nurse)</td>
<td>No</td>
<td>Community residential centers/half way houses</td>
<td>None specified</td>
</tr>
<tr>
<td>ME</td>
<td>Yes</td>
<td>Nurse delegation</td>
<td>One year FTE as a certified nurse’s aide (CNA)</td>
<td>Tenth grade competency level on the Test of Adult Basic Education (TABE)</td>
<td>Not less than 60 hours</td>
<td>Certified nursing assistant-medication (CNA-M)</td>
<td>Long term care nursing facilities, state mental health institutions, and assisted living</td>
<td>Four hours annually</td>
</tr>
<tr>
<td>KS</td>
<td>Yes</td>
<td>Nurse delegation</td>
<td>No high school or GED required; candidate must be a NA or a mental retardation professional</td>
<td>Reading at eighth grade level must be passed prior to taking course</td>
<td>60 hours</td>
<td>Yes</td>
<td>Adult care homes, including those for mentally retarded and hospital-based LTC units</td>
<td>Ten hours of training every two years</td>
</tr>
<tr>
<td>OR</td>
<td>Yes</td>
<td>Nurse delegation</td>
<td>None stated—candidate must have 9 months experience as a CNA</td>
<td>None stated</td>
<td>80 hours</td>
<td>Pass state administered exam to become certified</td>
<td>All settings but mostly LTC settings</td>
<td>Eight hours of training and 400 hours of paid employment as a CNA every two years</td>
</tr>
<tr>
<td>SD</td>
<td>Yes</td>
<td>Nurse delegation</td>
<td>High school education or equivalent</td>
<td>NA</td>
<td>20 to 80 hours</td>
<td>No, facilities issue certification of completion</td>
<td>All settings</td>
<td>Not by statute/rule; facilities create their own CE requirements based on the needs of the setting</td>
</tr>
<tr>
<td>MD</td>
<td>Yes</td>
<td>Nurse delegation requiring nurse supervision</td>
<td>None required</td>
<td>English reading and writing abilities</td>
<td>16 hours</td>
<td>No</td>
<td>Juvenile Justice, small group homes, schools, daycare, hospitals, correctional settings, and assisted living.</td>
<td>Clinical update every two years</td>
</tr>
</tbody>
</table>
As can be seen from the preceding table, unlike Massachusetts, none of the seven states that we contacted directly authorized unlicensed individuals to administer medication. Rather, all seven required unlicensed individuals to be supervised to some degree by a licensed professional using what is called a Nurse Delegation Model. Moreover, at least six of the seven states require more hours of training to administer medications than is required in Massachusetts, ranging from 16 total hours in Maryland to 80 hours in Oregon. Unlike Massachusetts, three of the seven states had continuing education requirements, one state required four hours of training annually, another required 10 hours of training every two years, and one state required eight hours of training and 400 hours of paid employment every two years. In addition, four of the seven states require more stringent education and prior experience levels for applicants than Massachusetts. One state requires applicants to have a high school diploma or equivalent, and three require applicants to be experienced certified nursing assistants or aides.

Officials from the Board of Registration in Nursing (BRN) and the Massachusetts Nurses Association (MNA) indicated that they believed that 12 hours of training that MAP participants receive in medication administration is inadequate because it should not be separated from training in overall nursing care, which requires two to four years or more of training. Also, MNA officials stated that, in their opinion, MAP treats medication administration as a task without considering the individual needs of the client who may be medically very fragile and receiving an array of other medications. MNA officials were also concerned that MAP gives the direct-care staff person responsibilities that are required of a professional with a clinical background. Further, these officials stated that MAP participants are not adequately trained to monitor patients once their medication has been administered and to recognize any adverse reactions that may occur. These officials told us that only a licensed person, such as a registered nurse or licensed practical nurse, would have the appropriate hours of training to adequately provide medication administration. Furthermore, MNA officials indicated that they were concerned that English
proficiency is not required, since this may affect the taking of medication orders over the telephone and the transcription of these medication orders onto medication sheets. In contrast, representatives from the American Red Cross (ARC) stated that this is the same training that the ARC provides to certified nursing assistants and believes it to be adequate.

**Recommendation:** DPH should consult with members of the BRN and MNA as well as other health care professionals both within Massachusetts and other states regarding MAP program eligibility, training, and continuing education requirements to determine the adequacy of these requirements. Based on this consultation, DPH should take whatever measures it deems appropriate to enhance the quality of MAP certified staff.

**Auditee’s Response:** DPH, DMH, and DMR officials stated, in part:

The survey of medication administration in other states is problematic because it did not examine programs similar to MAP. The information gathered was on institutional settings, such as long term care, and not community residential settings such as those that are overseen by MAP. When we surveyed mental retardation programs in the states surveyed by OSA...we found that only one state (Maine) had standards comparable to MAP and that the six other states had much lower standards than Massachusetts. In contrast to MAP, none of these six states had a standardized program, state curriculum, independent testing or certification, or recertification or continuing education in their mental retardation programs.

**Auditor’s Reply:** We disagree with the assertion that our survey was in any way “problematic” because it was limited to institutional settings and not community-based programs. In fact, our survey did include group homes, community residential centers, halfway houses, adult care homes and other non-institutional community-based programs. In its response, DPH, DMH, and DMR provided us with an addendum that they asserted is a survey of seven of the states we contacted who allow unlicensed individuals to administer medication in community-based homes housing mentally retarded citizens. Since the majority of the information in this survey conflicts with the information we independently obtained during our survey, we cannot comment on the information detailed in the addendum. However, the survey conducted by DPH, DMH, and DMR is less comprehensive than ours. For example, the departments only looked at individuals
residing in DMR community-based homes within these states, whereas our survey also included, as does MAP, facilities that have individuals within residential mental health programs.
Potential Deficiencies in the Direct Authorization Model Adopted for Administration of Medication to DMR/DMH Clients

Currently, the Department of Public Health (DPH) uses a Direct Authorization (DA) model to administer the Medication Administration Program (MAP). In the DA model, MAP-certified staff members administer medication directly to clients under a physician’s direction in accordance with 105 Code of Massachusetts Regulations (CMR) 700.003(F). This involves the following basic steps:

- Transcribing physicians’ prescription orders (either from written physician order sheets or via telephone) onto clients’ medication sheets
- Cross-checking orders to pharmacy labels
- Writing medical progress reports on clients
- Documenting removal of controlled, countable substances from the storage area
- Administering medication to consumers in accordance with a doctor’s instructions
- Documenting medication administration activities on the medication sheet
- Observing and reporting on any physical, emotional, or behavioral changes in the clients
- Contacting a consultant (physician, registered nurse, or pharmacist) in the event of a medical error or to seek advice

Additionally, if the physician orders vital signs monitoring for the client, the service provider is responsible for ensuring that its MAP-certified staff receive the supplemental training and are made proficient in a specific client’s vital signs monitoring requirements.

MAP coordinators who are registered nurses work at each of the Department of Mental Retardation’s (DMR) and the Department of Mental Health’s (DMH) 12 regional offices. MAP coordinators provide consultation and oversight of MAP, do not provide direct nursing care, delegate any nursing practices, and are not responsible for the medication practices of MAP certified staff. Also, under the DA model, DPH requires providers to have a consultant (licensed
physician, registered nurse, or pharmacist) available for staff to call 24 hours per day, seven days per week. If certified workers have questions regarding the medication orders for clients they call consultants for advice. Staff members also call consultants in the event of an occurrence of a medical error during the process of administering medication. Also, other nurses, such as the Visiting Nurses Association, administer medication to clients with severe medical problems that require complex administrations of medication such as insulin.

While the DA model may represent an efficient way of providing medication administration to consumers in community-based residences, one potential problem is the issue of liability. According to state law, nurses are accountable for the safety of the nursing care they deliver. Chapter 112, Section 80B, of the Massachusetts General Laws states, in part; “Each individual licensed to practice nursing in the commonwealth shall be directly accountable for safety of nursing care he delivers.” However, in the DA model the service provider, an independent contractor, is liable for the medication practices of its certified staff. DPH does not require contracted service providers to carry liability insurance coverage and since most providers are not-for-profit corporations, they are not liable for claims exceeding $20,000 in accordance with Chapter 231, Section 85K, of the General Laws, Limitation of Tort Liability of Certain Charitable Organizations, which states, in part:

It shall not constitute a defense to any cause of action based on tort brought against a corporation, trustees of a trust, or members of an association that said corporation, trust, or association is or at the time the cause of action arose was a charity; provided, that if the tort was committed in the course of any activity carried on to accomplish directly the charitable purposes of such corporation, trust, or association, liability in any such cause of action shall not exceed the sum of twenty thousand dollars exclusive of interest and costs.

As a result, consumers who may be harmed by mismedication under this model may not be equitably compensated for their losses.

The DA model could also impact the quality of direct care provided to consumers. Specifically, MAP certified staff are not licensed or trained in the profession of nursing and
therefore not legally allowed to treat clients beyond administering medication. As a result, they cannot provide a number of the patient care services that other health care professionals can provide. For example, neither cardiopulmonary resuscitation (CPR) nor first aid training are required under MAP. Certified staff do receive limited training on how to observe and identify symptoms of illness and how to report any physical, emotional, or behavioral changes in clients. However, they must report these observances directly to the designated consultant on call at the time or the client’s primary care physician and cannot address these problems as expeditiously as a health care professional.

In order to advise licensed nurses who were working for DMR or DMH of their responsibilities and limitations on the services they can provide in this model, the Board of Registration in Nursing (BRN) on February 16, 1994 issued an Advisory Ruling entitled “Nursing Practice Related to Medication Administration by Certified Program Staff in Community Residences—Departments of Mental Health and Retardation,” clarifying their scope of practice of nurses in the DA model. The Advisory Ruling in regard to the “Teaching the Curriculum for Medication Administration Certification” states, the following:

- Nurses deemed qualified by the DMH or DMR to teach the established program of instruction for medication administration may instruct unlicensed program staff in the didactic and practical components of the program leading to certification in medication administration.

- The nurse instructor does not bear on-going accountability for the practice of the staff person who is certified under the standards established by DMR and/or DMH.

- Nurses who have not been trained as instructors for the DMR/DMH medication administration program should not participate in supervising or monitoring the initial administration of medication to clients by newly certified staff.

- Monitoring of initial medication administration is not a formal part of the DMR or DMH training program. However, the Board [BRN] strongly supports such supervision by qualified nurse instructors. This does not constitute delegation of medication administration by the nurse instructor.
The Advisory Ruling in regard to “Accountability for Medication Administration to Clients for Whose Care the Nurse is Responsible” states, in part:

- Administration of medications by certified program staff to clients for whom the certified staff person has direct care responsibility, is not considered delegation and/or supervision, as defined in 244 CMR 3.05, by a nurse who is providing care to other clients in the same residence.

- A licensed nurse is only accountable for the medications he/she administers. A nurse is not accountable for medications administered by certified direct care staff.

In regard to “Providing Technical Assistance and Advice 115 CMR 6.06 (6) (f) and 104 CMR 15.03 (6) (h) (9),” the Advisory Ruling states:

- Nurses who are employed by DMR and/or DMH to provide or arrange for technical assistance and advice…shall provide assistance about systems related to medication administration issues as required. Examples of systems include, but are not limited to transcribing, ordering, procuring, documenting, destroying and storing of medications.

- Questions about client care problems related to medications should be directed or referred to the appropriate licensed practitioner (MD/NP/PC) either via telephone, office visit, clinic visit, or emergency room visit, or the appropriate emergency response system, per Department of Public Health policies.

Since the inception of MAP, both the Massachusetts Nurses Association (MNA) and BRN have expressed concerns about MAP and, in particular, the DA model utilized to administer medication. Both MNA and BRN have been concerned about the health and safety of the DMR and DMH clients because the staff administering the medication were inadequately trained and supervised and these clients’ health was put at risk; many clients were already medically fragile.

In MNA’s opinion, the implementation of MAP and the utilization of the DA model has reduced medication administration to a task and has isolated this function from nursing practices, which includes medication administration and the delivery of a wide range of nursing care involving evaluations and clinical decision making about a person’s health in order to achieve quality nursing care. Furthermore, MNA officials told us that direct care staff are being given nursing responsibilities who are not qualified to practice nursing, which can require two to four
years of training. MNA officials cited instances in which direct care staff had to make decisions about PRN ("as needed") prescription medications and could not because they could not determine when the "need" arose. MNA officials are also concerned about unqualified staff being responsible for the transcription of orders over the phone, as physicians do not always know they are dealing with unlicensed staff. MNA officials added that intake of psychotropic drugs can have dangerous consequences. In many instances, a nurse is the only person qualified to make judgments and decisions indicative of a drug reaction or if the client may simply need the environment made safe or adjusted. Furthermore, they stated that nurses are accountable for their nursing care, and that only nurses can adequately perform the administration of medication to these disabled clients, and that the current MAP model should be abolished.

BRN expressed the following concerns about the inadequacy of the DA model:

- The program was staffed by persons who were inadequately educated and supervised to administer medications
- The health and safety of clients who were medically fragile were being put at risk
- There was a lack of ongoing supervision by licensed professional staff, in particular in the passing of new prescription medications
- The regulations did not provide for the making of client assessments or evaluations of medication efficacy

Because of these concerns, both BRN and MNA brought the issues to the attention of the state Legislature. For example, in a letter to the House Chair of the Health Care Committee on July 28, 1994, the BRN stated:

The Board is interested in pursuing an amendment to House bill 3204 (S.485) which would require that medication administration to clients in DMR and DMH community programs be nurse-taught, nurse-managed and nurse-supervised, under regulations promulgated cooperatively by the Board of Registration in Nursing and the Departments of Public Health, Mental Health and Mental Retardation.

Moreover, on May 15, 1997, MNA made the following statements to the state Legislature:

As you know, unlicensed direct care staff have been administering medications to clients in group homes for a number of years. However, the newly promulgated regulations,
which teach direct care staff, are flawed and dangerous. They ignore complexity of medications, complexity of illness, cognitive ability to verbalize changes, aging issues and base programs simply on the geography of the client’s residence, not an assessment of need.

I want to articulate that MNA has been very diligent in looking for solutions, so medications can be managed in group homes, safely and within a professional standard that assures health and well being, while not violating independent living. You as a legislature should be very concerned about this major public policy change that has occurred without your knowledge or consent. This program has been formulated simply through regulation, and the state intends to expand it despite our oppositions based on sound clinical knowledge, expertise and scientific evidence to back up our position.

An oversight model, known as the Professional Oversight Model (POM), was considered as an alternative to the DA. POM was described by DMR officials as a model different from the DA model, even though in effect, its design involved an additional layer of nursing oversight to the DA model. The POM was proposed in a Progress Report more commonly known as the MAP Improvement Plan submitted to the Chairman of the Joint Legislative Committee on Health Care on January 12, 1998. The Chairman had previously requested a MAP Progress Report from the Commissioners of DPH, DMH, and DMR. The MAP Improvement Plan included nine steps for the overall improvement of the health and safety standards of MAP. The most important being step number one, “Move to a professional oversight model for medication administration,” to be funded and implemented in fiscal year 1999. The professional oversight model has as its basis the DA model but, in addition, licensed professional staff would provide oversight of staff and MAP. Specifically, registered nurses would provide ongoing training of certified direct care staff, provide technical assistance relating to MAP, monitor and manage medication administration systems, and manage quality assurance in registered community residential and day programs.

The MAP Improvement Plan describes the professional oversight model as follows:

Under the professional oversight model, certified staff will retain direct authorization to administer medications under the direct orders of a client’s health care provider. In accordance with the Board of Registration in Nursing’s “Advisory Ruling on Nursing Practice Related to Medication Administration by Certified Program Staff,” dated June
17, 1997, registered nurses involved in this model will monitor and report on, but will not be responsible for, certified staff’s medication practices. In addition, registered nurses will be permitted to monitor the initial medication administration by certified staff and to monitor the medication administration systems, including, but not limited to, transcribing, ordering, procuring, documenting, destroying and storing of medications. This model is distinct from a nurse delegation model in which a nurse, in addition to the health care provider, assesses a consumer’s needs, develops a nursing plan of care (in addition to the health care provider’s treatment plan) and then implements and evaluates that treatment plan on an ongoing basis. In the professional oversight model the responsibility for the consumer’s care remains with the health care provider, not with the nurse. The health care provider makes the assessment, develops and implements the treatment plan, and provides ongoing evaluation. In contrast to the nurse delegation model, the consumer’s relationship with his/her provider is not altered in the professional oversight model.

BRN officials stated that they supported the proposed improvements to MAP as well as POM, by stating, “The professional oversight model for medication administration is fully consistent with the Board’s recommendations for MAP and with MGL Chapter 112, Section 80B [of the General Laws].” BRN supported the proposed improvements outlined in the MAP Improvement Plan because it would strengthen MAP’s safety and quality, the lack of supervision of the program in particular, and when new medications were being distributed. Although BRN has supported the new model, it believes the model would be further strengthened by the development of regulations and that “the public can be best assured that the Departments are committed to making these changes to MAP if the proposals are given the force of regulation.” As of the end of our audit period, POM had not been implemented nor have new regulations regarding MAP been promulgated.

In contrast, MNA officials have stated that quality of care of DMR and DMH clients will not be met with the implementation of POM. MNA officials stated that the model lacks consumer protection because there remains a lack of accountability in the administration of medication for the disabled. Also, POM maintains the same “arms length relationship of nurse to client” as its premise. MNA officials told us that they made a suggestion to the Legislature that they be allowed to design an acceptable community nursing care model that would be accountable for clients’ total health care, including the administration of medication, but this request was not
granted. MNA officials told us that, in the long run, if implemented their model may be less expensive than either the DA model or POM because since its inception in 1993, MAP has been under constant revision. However, MNA officials did not give us any documentation to substantiate this assertion.

As part of improvements made to MAP, full-time registered nurses and licensed practical nurses have been assigned at regional offices of DMR and DMH as MAP coordinators and have been providing technical assistance and oversight since September 1998. However, according to MNA officials, licensed practical nurses are being used as direct care staff at the state operated homes and are not administering medication under their license, which is creating both legal and regulatory problems. MNA’s contention is that many clients of DMR and DMH, due to the nature of their illnesses and numerous other health problems, require total nursing care that the DA model and POM do not provide.

Importantly, MNA officials believe that clients are not receiving quality nursing care and continue to advocate for a community nursing care model for medication administration to these groups of disabled clients. They have stated that nursing research supports that the presence of nurses in assessing patients’ health increases the likelihood of positive outcomes.

According to DMH and DMR officials, the POM has not been fully implemented due to a lack of funding. Without implementation of POM, BRN is gravely concerned about the lack of nursing supervision over MAP and the certified staff administering medication. These officials told us that the clients of DMR and DMH are initially more vulnerable than people outside the realm of these institutions. For one thing, they may not have the cognitive ability to recognize or communicate the effects of certain drugs that they are dizzy, nauseated, itchy, have blurred vision, and so forth after taking medication. Furthermore, clients that additionally receive other complex medications, such as insulin or feedings via G-tube/J-tube, are at a very high risk of developing complications if the proper balance of medication is not administered. For example,
BRN officials have stated that diabetics require frequent blood glucose monitoring to avoid falling into immediate life threatening situations (i.e., hyperglycemia) or developing such complications as blindness, heart disease, kidney failure, and nerve damage, which can ultimately lead to limb amputations.

**Auditee’s Response:** DPH, DMH and DMR provided the following general comments:

Overall, the issues raised in the report are procedural and administrative in nature. While these issues may have an impact on the quality of MAP oversight processes, it is important to note that they do not have a direct bearing on outcomes for individuals served by the community programs overseen by MAP. Rather, the quality of oversight processes is related to the ability to gather and disseminate information concerning potential systemic problems. We believe that the quality and extent of oversight in MAP, along with the built-in safeguards, ensures the safety of medication administration in community programs. Safe medication administration was the intended goal of the original regulations promulgated in 1993 and we are gratified by the success of MAP in achieving that goal.

We would submit that American Medical Association estimate for medication error rates in medical facilities is not appropriate predictor of expected medication occurrence rates in MAP. The AMA figure is based on different measures than in MAP (i.e., “errors” vs. “occurrences”) and different populations and settings (i.e., individuals undergoing acute care in medical institutions vs. medically stable individuals in residential settings).

- In contrast to the statement in the report, we have not characterized the Clinical Review process as “primarily an educational process”. The Clinical Review process has always been represented as an oversight function.

- We believe that the number of clinical reviews that can be done by a single Clinical Reviewer is overestimated in the report. The estimate appears to be based on the estimated time for fieldwork and does not include time for clinical review analysis, follow up and processing, MOR follow up and processing and other duties of the Clinical Reviewer. In addition, the estimated number of workdays in a year appears not to account for sick time and other leave.

- The question of how and when sites are selected for review was answered in writing to the OSA.

**Auditor’s Reply:** We do not agree that the administrative and procedural problems relative to MAP that we identified during our audit do not directly impact the consumers being served in the department’s residential programs. Clearly, deficiencies in MAP’s monitoring can result in inaccurate and incomplete information relative to medication administration activities being
performed in DPH, DMH, and DMR’s programs. This deficiency impacts the ability of DPH, DMH, and DMR to make informed and appropriate decisions relative to the administration of medications in their community-based programs. Our report acknowledges the fact that American Medical Association’s (AMA) estimate is for medical facilities and not residential programs. We used this study to merely show that a certain number of errors or inappropriate medication occurrences can be expected in settings where medication is being administered. Since the AMA’s figure is for medication errors alone and not all medication administration occurrences, it seems likely that if all medication administration occurrences were identified including medication errors, the 3% rate in the AMA report could be higher. Our concern is that a significant number of programs housing DMH and DMR consumers have never filed a Medication Occurrence Report raising a question as to whether all medication occurrences are being properly reported by these programs. This issue is significant and should be examined by the departments.

As stated in our report, the DPH officials did in fact characterize DPH’s clinical review process as being primarily an educational process. If so, and DPH, DMH, and DMR utilize the clinical review process as an oversight function, then we urge the department to address the deficiencies we identified within this process in order to ensure proper program oversight. The exact number of reviews the individual DPH has conducting its clinical reviews is not the argument. However, our point is that if, as DPH contends in its response, its clinical review process is used for program oversight, then one person could not effectively be performing this program oversight function.
APPENDIX A

Ad Hoc Panel Recommendations for Medication Administration Program

Medication Delivery and Security:

*1. Note if losses have been appropriately reported to DPH.
*2. Survey the use of phone orders for medication by certified staff.
*3. Review consumer/client records to measure if a change in a medication dose results in a change in the prescription label.
*4. Monitor the time from a change in medication order to the time of the filling of the prescription.
*5. Measure inappropriate packaging of medications.
*6. Identify the various schedules (II-VI) of medications administered in both DMH and DMR community residential programs.

Staff Training and Certifications:

1. Complete a PLINE (Primary Language Is Not English) survey to determine the percentage of direct care staff whose primary language is not English.
2. Survey staff experience through focus groups.
3. Survey staff, registered nurses, and vendors regarding the utilization of training to determine weaknesses, if any, of the training program.

Use of the Medication Occurrence Reporting System for Medication Errors:

1. Follow up with medication errors to determine if the reason for the occurrence is a lack of understanding due to English as a second language.
2. Survey the turnover rate of certified staff in the programs and correlate the turnover rate with the Medication Occurrence Reporting.

Inspection and Oversight of MAP:

*1. Review progress notes to determine if an event results in the contract of the health care provider, a response from the health care provider, and if there is a change in medication and/or treatment.
2. Measure events not perceived by the Medication Occurrence Reporting system, e.g., a visit to the emergency room for medication side effects.

Impact on Clients/Consumers and Staff:

1. Determine the impact of MAP on staff through the use of focus groups.
2. Determine the impact of MAP on clients/consumers through interviews of clients/consumers, families, and friends.

Quality Assurance:

*1. Review progress notes to determine if use of PRN (as needed) medications is documented.

APPENDIX A (Continued)
*2. Review ISP/PSTP to determine if medication administration is part of an individual’s plan of care.
*3. Review health care provider’s orders to determine if PRN (as needed) have specific instructions for use.
*4. Complete a random survey to determine the percentage of consumers/clients with a primary care physician.
*5. Survey the different classifications of medications used throughout MAP sites distinguishing between DMH and DMR residences.
*6. Complete a random survey to determine the percentage of consumer/clients who self-medicate.
*7. Complete a risk assessment for each consumer/client.

*Recommendations that have been implemented
APPENDIX B

Recommendations and Depositions by HPAOB

The following is a list of the four recommendations made by the House Post Audit and Oversight Bureau (HPAOB) entitled “Review: Medication Administration Program: DMR, DMH” and the disposition of these recommendations as of the end of our audit fieldwork.

Recommendation No. 1: The Department of Public Health (DPH) should establish a Quality Review Team, including Massachusetts Nurses Association and the Professional Nurses Association to ensure the integrity and the effective operation of the Medication Administration Program (MAP). This group should meet regularly with affected agencies and commissioners to discuss planning and implementation issues.

Current Disposition: According to DPH officials, the departments had a Quality Review Team for MAP long before the HPAOB review, specifically since implementation of the regulations. They added that this Quality Review Team remains in effect to the present day, which is an addition to the MAP Advisory Group. The three departments in their monthly progress report submitted to HPAOB on September 28, 1998 for July and August 1998 stated the following regarding the Quality Review Team:

DMH’s Chief of Staff, DMR’s Assistant Commissioner for Quality Management, DPH’s Director of the Drug Control Program, the DPH MAP Program Coordinator and other DMH/DMR/DPH staff continue to meet at least quarterly to discuss the findings of the clinical review process and other pertinent issues and to plan and implement components of the Improvement Plan. These individuals, in conjunction with Licensing Survey and Certification, MAP Coordinators and the DPH team of reviewers and inspectors function as the “Quality Review Team.” This team continues to be active in inspections, reviews, investigations and follow up activities.

Although the Board of Registration in Nursing historically has not participated as an official member of the review team, the Board does provide the Departments with advice, guidance and recommendations on various MAP related issues including, but not limited to, defining nursing’s scope of practice in MAP, and nursing’s liability exposure, if any. In addition, the Board is an active member of the MAP advisory group. The Departments do agree with the Bureau that the Board of Registration in Nursing has expertise and knowledge that would greatly benefit the review team. Therefore, the

APPENDIX B (Continued)
Departments plan to include the Board in upcoming meetings. The Board already participates in the MAP Advisory Panel.

An open meeting with the Commissioners was held at the end of July 1997. The meeting provided MNA, AFSCME, service providers, trainers, MAP Coordinators and other interested parties the opportunity to share their concerns, opinions and recommendations. Over the past two years the three Commissioners have met with various members of the MNA and other labor relations organizations to discuss their specific concerns and recommendations. The commissioners maintain an open door policy for these groups and all interested parties.

The MNA has been a member of the MAP Advisory Group and the Ad Hoc Panel on Development of Evaluation Measures. MNA and other labor relations groups such as AFSCME have always had access to all draft policies and procedures. The Departments continue to welcome input from these groups and all other interested parties regarding MAP related issues. Recommendations pertinent to a specific policy, procedure or process will continue to be incorporated when found to be applicable for our populations in the community setting.

**Recommendation No. 2:** The Department of Mental Health (DMH) and the Department of Mental Retardation (DMR) should agree to spot checks and inspections of the MAP program’s operation by the Quality Review Team and report findings to the HPAOB and DPH.

**Current Disposition:** According to both DMH and DMR officials, spot checks are being conducted by the DMH Licensing and DMR Survey and Certification Staff, and Technical Assistance Tool reviews are conducted by MAP Coordinators and the DPH Clinical Reviewer. However, the findings uncovered during these checks are not forwarded to HPAOB. Agency officials stated that they provided an explanation to HPAOB on the first monthly progress report forwarded September 28, 1998 on how spot checks would be conducted. Section 2.b. of the progress report stated, the following:

DMH and DMR plan to perform regularly scheduled and random site visits. The Departments will discuss this issue with provider agency organization representatives at the September 24 meeting. Further institutionalization of such visits by the Quality Review Team will be discussed at Review Team meetings before implementation.”

**APPENDIX B (Continued)**
When we asked DMR and DMH officials why findings were not reported to HPAOB, they told us that the Bureau did not request that findings be forwarded to the Bureau or included with the monthly reports. They added that the feedback they received did not indicate that findings be forwarded.

**Recommendation No. 3:** DMH and DMR should agree to provide monthly progress reports on the MAP program to HPAOB.

**Current Disposition:** DPH, DMH, and DMR began to submit monthly progress reports to HPAOB in September 1998 (the first report included the activities for July and August). As of April 2000, HPAOB requested that the agencies submit only quarterly reports; the first quarterly report is due July 2000.

**Recommendation No. 4:** The Conrad Simon case should be reinvestigated by the Disabled Persons Protection Commission to re-evaluate the inconsistency in information reported.

**Current Disposition:** The results of the reinvestigation of the Conrad Simon case by the Disabled Persons Protection Commission were reported directly to HPAOB on May 3, 2000.
# APPENDIX C

## Audit Sites Visited

<table>
<thead>
<tr>
<th>Agency</th>
<th>Program Location</th>
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<tbody>
<tr>
<td><strong>Department of Mental Health:</strong></td>
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<tr>
<td>Central Office</td>
<td>25 Staniford Street, Boston</td>
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<tr>
<td>South Metro Office</td>
<td>460 Quincy Avenue, Quincy</td>
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<tr>
<td><strong>Department of Mental Retardation:</strong></td>
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<td>Central Office</td>
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<td><strong>Department of Public Health:</strong></td>
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<td>Central Office</td>
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<td>Division of Food and Drugs</td>
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<td>Advocates, Inc.</td>
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<td>19 Karal Drive, Framingham</td>
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<td>Bay Cove Human Services</td>
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<td>599 American Legion Road, Roslindale</td>
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<td>Community Healthlink, Inc.</td>
<td>72 Jaques Street, Worcester</td>
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<td>2 Anthony’s Way, Sandwich</td>
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<td>Fellowship Health Resources, Inc.</td>
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<td>Human Services Options, Inc.</td>
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### APPENDIX C (Continued)

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