BACKGROUND:
The Public Health Division, Healthcare Regulation and Quality Improvement (HCRQI) program ensures that a safe and healthy environment is provided by over 500 health related facilities and agencies. Permanent administrative rules for IHCAs have been filed to address the provisions of SB 158 and HB 2650 passed during the 2011 Legislative Session, as well as aligning the current rules with other health care agency rules.

SUMMARY OF CHANGES:
These rules address the IHCA licensing application and review process, new classifications for IHCA’s, inspections, complaint investigations, surveys and background check requirements for owners, administrators and staff who have direct contact with clients. In addition, clarification has been added with regard to providing medication and nursing services and additional provisions for organizational responsibilities, requirements for disclosure statements, caregiver qualifications, client records, service plans, and quality improvement activities. Some definitions have been changed or added, so agencies need to take a moment to carefully review.

Classification (NEW)
There are now four different classifications for IHCA licensure based on the type of services provided:

(a) Limited; An agency that provides personal care services that may include medication reminding but does not provide medication assistance, medication administration, or nursing services;
(b) Basic; An agency that provides personal care services that may include medication reminding and medication assistance but does not provide medication administration or nursing services;
(c) Intermediate; An agency that provides personal care services that may include medication reminding, medication assistance and medication administration but does not provide nursing services; or
(d) Comprehensive; An agency that provides personal care services that may include medication reminding, medication assistance, medication administration and nursing services.

Medication services training for caregivers employed by an agency classified as Basic, Intermediate or Comprehensive must be provided by one of the following:

1. A “qualified entity” which is a medication training program approved by the HCRQI program; or
2. A “qualified individual” who is a person who has completed a medication training program approved by the HCRQI program; or
3. A “qualified individual” who is currently licensed as a registered nurse, practical nurse, physician assistant, or pharmacist; or
4. Another health care professional who is approved as a “qualified individual” by the HCRQI program.

An agency licensed by the Division cannot use a classification title in its advertising, publicity, or any other form of communication other than what the agency is licensed to provide.

Changes to the License Application and Licensure Process
Application (updated):
An owner or administrator who has direct contact with a client must submit information to the HCRQI program for the purposes of conducting a criminal records check. The HCRQI program will conduct the criminal records check at the time of application for a person who applies for a license on or after July 1, 2012 and every three years thereafter, or by July 1, 2013 for an agency that is licensed on or before July 1, 2012 and every three years thereafter.

If any of the information in an agency’s most recent application changes other than at the time of annual renewal, a revised application must be submitted to the Division within 30 days of the change. If an agency requests a change to administrator, agency classification, branch and subunit; or geographic service area exceeding one hour’s travel time, it must first receive approval from the HCRQI program before implementing.

Application approval (new):
The HCRQI program will notify applicants in writing if a license application is approved or denied. An agency must conspicuously post its license in an office that is viewable by the public.

Denial of application (new):
If the Division intends to deny a license application, it will issue a Notice of Proposed Denial of License Application in accordance with ORS 183.411 through 183.470.

Fees (updated):
All application fees are now non-refundable.

Surveys (Updated)
A new provision has been added with regard to accepting the certification or accreditation from a federal agency or accrediting body in lieu of the HCRQI program conducting a survey. Currently, no certification or accreditation exists for in-home care agencies, but language has been added in case this changes in the future.

In lieu of an on-site inspection required by rule, the HCRQI program may accept a certification or accreditation from a federal agency or an accrediting body approved by the Division that state licensing standards have been met if an IHCA:

1. Notifies the Division to participate in any exit interview conducted by the federal agency or accrediting body; and
2. Provides copies of all documentation concerning the certification or accreditation requested by the Division.

Following a survey, HCRQI staff may conduct an exit conference with an agency owner, administrator, or designee. During the exit conference, HCRQI staff must:

1. Inform the agency owner, administrator or designee of the preliminary findings of the inspection; and
2. Give the owner, administrator, or designee a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings.

HCRQI staff must prepare and provide the agency owner or administrator specific and timely written notice of the findings.

If no deficiencies are found during a survey, the HCRQI program will issue written findings to the agency owner indicating that fact.
If deficiencies are found, the HCRQI program will take informal or formal enforcement action in accordance with the rules (identified further in this document).

Complaints (Updated)
This rule has been updated to reflect that an employee with knowledge of a violation of laws or rules pertaining to IHCAs must use the reporting procedure established by the IHCA before notifying the HCRQI program or other state agency. An employee may report issues directly to HCRQI program or other state agency if the employee believes that a client’s health or safety is in immediate jeopardy.

If a complaint involves an allegation of criminal conduct or an allegation that is within the jurisdiction of another local, state, or federal agency, the HCRQI program will refer the matter to that agency.

Services Provided (UPDATED)
Language regarding medication reminding services has been clarified. An agency may provide medication reminding services to persons who are able to self-direct but must document the client’s knowledge of the following information using the “Self-Direct Evaluation Tool” prescribed by the HCRQI program (attached):

- The reason why each medication is taken;
- The amount or dose of each medication that needs to be taken;
- The route the medication needs to be taken; and
- The time of day each medication needs to be taken.

A copy of this form, signed by the client, when an agency has determined the client can self administer medications must be kept on file.

An agency must re-evaluate whether a client can continue to self-direct at a minimum of every 90 days. If a client can no longer self-direct, arrangements must be made to transfer the client to an ICHA with a higher license classification within 30 days if the agency providing current services is not classified as such.

If an agency has clients who receive only housekeeping and support services, the agency is not required to comply with the following requirements: service plan, caregiver qualifications, medication services, nursing services, client records or quality improvement activities.

Organization, Administration, and Personnel (Updated)
An agency must keep all its in-home care agency records separate and distinct from other business entities.

Provisions have been made to allow a caregiver to accompany a client outside of the IHC geographic service area if all of the following provisions are met:

1. A client has requested an agency caregiver to accompany the client; and the travel plans are described and documented in the client’s service plan.
2. The caregiver who accompanies the client outside the geographic service area must:
   (a) Document all services and care provided to the client on a daily basis;
   (b) Report to the agency administrator or designee either by phone or e-mail the status of the client before leaving the geographic service area and immediately upon return;
   (c) Check-in with the agency administrator no less than once per week if the travel results in the client and caregiver being gone for more than one week; and
(d) Be certified in Cardiopulmonary Resuscitation (CPR); and (e) contact the agency administrator or designee immediately if the client’s condition changes while traveling.

3. An IHCA must develop policies and procedures which address what caregivers must do when the client’s condition changes while the client and caregiver are out of the agency’s geographic service area.

An office that provides services generally exceeding one hour of travel time outside an IHCA’s geographic service area will be considered a subunit.

Clarification has been provided on the qualifications of an administrator in terms of what constitutes management experience (see definition in rule.)

Provisions for contracting with individuals or with another agency to provide in-home care services have been removed from rule. Administrative rules require that an agency have administrative and supervisory oversight and must control and be responsible for all services provided. This contradicts with employment laws which require that for someone to be considered a contractor they must be 1) free from the right of another to control how services are performed and 2) that the worker operates independently. Further information on this issue can be obtained from contacting the Employment Department at (503) 947-1520 or visit: [http://www.oregonindependentcontractors.com/IC/pages/icn-brochure-textonly.aspx](http://www.oregonindependentcontractors.com/IC/pages/icn-brochure-textonly.aspx).

Clients’ Rights (Updated)
An agency must provide each client a written notice the client’s rights as part of the disclosure statement.

Service Plan (Updated)
The service plan no longer needs to identify the professional discipline of persons providing services.

Information related to caregiver supervision has been moved to this section and the term “supervisory visit” deleted. An ‘initial visit’ must be conducted by an IHCA administrator or designee within 30 days of the initiation of services to evaluate a caregiver’s compliance with the service plan and to assess the client’s satisfaction. The initial visit must occur between the 7th & 30th day. An initial visit is not required if a client cancels service on or before the 30th day, a client is residing in a nursing facility or hospital, or a client refuses.

During a quarterly monitoring visit, an IHCA administrator or designee must also determine whether a client is satisfied with his or her relationship with the caregiver(s).

If services are provided in a non-residential setting, the monitoring visit must occur in the same setting that services are provided.

Caregiver Qualifications and Requirements (Updated)
Caregivers must complete training and have their competency evaluated and documented by the administrator or designee. Caregiver training must now include providing basic non-injectable medication services as described in the Medication Services rule.

Caregivers must receive a minimum of six hours of education related to caregiver duties annually. If a caregiver provides medication administration to a client, one additional hour of education is required annually related to providing medication administration.

Medication Services (Updated)
The Medication Services rule has been revised to clarify the following issues:
Secondary Containers
If a client representative or family member performs the task of filling secondary medication containers from which an agency caregiver is supposed to administer medications, the IHCA must obtain a signed agreement from the client representative or family member that identifies the client representative or family member must:

1. Provide a list of the client’s medication and a physical description of each medication with any special instructions. The list must be updated when changes to the client’s medications are made;
2. Keep the original labeled medication containers in the home for verification should the caregiver have questions; and
3. Use closed medication secondary containers designed and manufactured for that purpose. The secondary containers and all removal compartments must be labeled with the client’s name, specific time the medications in each compartment are to be taken, the date and time the secondary container was filled, and the name of the individual who filled the container.

Written or Telephone Orders
For agencies providing medication services, staff must obtain written or telephone orders from a physician or other legally recognized practitioner for all medications managed or administered by an agency and for any changes to those medications. The written orders must be signed or confirmed by a physician or practitioner. Telephone orders must be immediately recorded, dated, and signed by agency staff, and transmitted within 72 hours to the physician or practitioner for confirmation. Orders that have been signed or confirmed by the physician or practitioner must be incorporated into the client’s record within 30 days.

Appropriate Medication Administration
An agency administrator shall be responsible for developing and implementing safe and appropriate medication administration delivery systems and policies and procedures for three new areas:

1. Provisions to ensure that each client receives the right medication, in the right amount, by the right route, and at the right time;
2. Provisions to ensure storage of medications at appropriate temperatures based on the manufacturer’s recommendations; and
3. Provisions to ensure the security and integrity of narcotics and controlled substances.

Evaluation of Client’s Medication Regimen
Visits by a registered nurse to evaluate a client’s medication regimen and the provision of medication administration services must be conducted and documented at least every 90 days for each client receiving medication administration services.

Medication Training
Medication training for agency caregivers must now include techniques and methods to ensure safe and accurate medication administration.

Nursing Services (Updated)
The Nursing Services rule remains primarily the same. It is important to note that the HCRQI program expects that nurses providing services understand rules for their profession, specifically administrative rules relating to “Standards for Community-Based Care Registered Nurse Delegation” (OAR 851-047) from which this section was developed.
A client’s record shall contain documentation that all requirements within OAR 851-047 have been met, including but not limited to: assessment, instruction, observation, supervision, and re-evaluation.

The provision of nursing services must be documented by the individual(s) providing the service(s) or performing the task(s). The documentation shall include the service(s) or task(s) completed, the date and signature of the individual(s) performing the service(s) or task(s), and shall be maintained in accordance with an agency’s policies and procedures.

For all medications and medical treatments managed or administered by an agency under this rule, and for any changes to those medications or medical treatments, a registered nurse must obtain written or telephone orders from a physician or other legally recognized practitioner. Written orders must be signed or confirmed by a physician or practitioner. Telephone orders must be immediately recorded, dated, and signed by the registered nurse, and transmitted within 72 hours to the physician or practitioner for confirmation. The orders that have been signed or confirmed by the physician or practitioner must be incorporated into the client's record within 30 days.

**Client Records (Updated)**

Client records are no longer required if the client **only** receives housekeeping or support services.

The HCRQI program has clarified the term ‘authenticated.’ For purposes of client records, authenticated means verification by the author that an entry in the client record is genuine. Electronic authentication is acceptable as long as there is a process for reconstruction of the information and there are safeguards to prevent unauthorized access to the records.

In an effort to coordinate services and care with other providers (e.g. hospice, home health, and family members) charting notes within a client’s home may be shared, as permitted by law.

**Quality Improvement (Updated)**

An agency must establish and maintain an effective, agency wide quality assessment and performance improvement program that evaluates and monitors the quality, safety and appropriateness of services provided by the agency. This program shall include at a minimum:

1. A method to identify, analyze and correct adverse events;
2. A method to select and track quality indicators by high risk, high volume, problem prone areas and by the effect on client safety and quality of care;
3. The quality improvement activities shall be conducted by a committee comprised of, at a minimum, agency administrative staff, an agency caregiver, and if the agency is classified as an intermediate or comprehensive agency, an agency registered nurse; and

Quality improvement activities shall be conducted and documented at least quarterly.

**Criminal Records Checks (NEW)**

In accordance with ORS 443.004, several changes have now been implemented for conducting criminal background checks. Specific definitions exist for the following terms and IHCAs should carefully review:

- “Direct contact with”;
- “Disqualifying condition”;
- “Subject individual” (SI);
- “Vendor”; and
- “Weighing test.”
An agency must conduct a criminal records check before hiring a subject individual (SI) and before allowing an SI to volunteer to provide services on behalf of the agency, if an SI will have direct contact with a client of the agency.

An SI who has or will have direct contact with a recipient of in-home care services may not be employed or volunteer with an agency in any capacity if the criminal records check conducted reveals the SI has been convicted of a crime as described in ORS 443.004(3) (see attached list of crimes.)

An agency must have a policy on criminal records check requirements that shall include weighing test actions should the records check screening indicate that an SI has been convicted for crimes against an individual or property other than those identified in ORS 443.004(3). The policy must include the following provisions for performing a weighing test:

1. The agency must consider circumstances regarding the nature of potentially disqualifying convictions and conditions including but not limited to:
   (A) The details of incidents leading to the charges of potentially disqualifying convictions or resulting in potentially disqualifying conditions;
   (B) The age of the SI at the time of the potentially disqualifying convictions or conditions;
   (C) Facts that support the convictions or potentially disqualifying conditions; and
   (D) Passage of time since commission of the potentially disqualifying convictions or conditions.

2. Other factors that should be considered when available include but are not limited to:
   (A) Other information related to criminal activity including charges, arrests, pending indictments and convictions. Other behavior involving contact with law enforcement may also be reviewed if information is relevant to other criminal records or shows a pattern relevant to criminal history;
   (B) Periods of incarceration;
   (C) Status of and compliance with parole, post-prison supervision or probation;
   (D) Evidence of alcohol or drug issues directly related to criminal activity or potentially disqualifying conditions;
   (E) Evidence of other treatment or rehabilitation related to criminal activity or potentially disqualifying conditions;
   (F) Likelihood of repetition of criminal behavior or behaviors leading to potentially disqualifying conditions, including but not limited to patterns of criminal activity or behavior;
   (G) Changes in circumstances subsequent to the criminal activity or disqualifying conditions including but not limited to:
      (i) History of high school, college or other education related accomplishments;
      (ii) Work history (employee or volunteer);
      (iii) History regarding licensure, certification or training for licensure or certification; or (iv) Written recommendations from current or past employers;
   (H) Indication of the SI’s cooperation, honesty or the making of a false statement during the criminal records check process, including acknowledgment and acceptance of responsibility of criminal activity and potentially disqualifying conditions.

3. An agency must consider the relevancy of an SI’s criminal activity or potentially disqualifying conditions to the paid or volunteer position, or to the environment in which the SI will work, especially, but not exclusively:
   (A) Access to medication;
   (B) Access to clients’ personal information;
(C) Access to vulnerable populations.

An agency must document the weighing test and place in the employee’s file.

A criminal records check must be performed by either:
1. the Department of Human Services, Background Check Unit; or
2. a vendor that is accredited by the National Association of Professional Background Screeners (NAPBS); or
3. meets the following criteria:
   (i) Has been in business for at least two years;
   (ii) Has a current business license and private investigator license, if required in the company’s home state; and
   (iii) Maintains an errors and omissions insurance policy in an amount not less than $1,000,000.

An agency may use the Oregon State Police, Open Records Unit in order to fulfill the state records requirement for a criminal records check, however, an agency must still complete a nationwide check through a qualified vendor.

A criminal records check must include the following:
1. Name and address history trace;
2. Verification that the SI’s records have been correctly identified, via date of birth check and Social Security number trace;
3. A local criminal records check, including city and county records for SI’s places of residence for the last seven years;
4. A nationwide multijurisdictional criminal database search, including state and federal records;
5. A nationwide sex offender registry search;
6. The name and contact information of the vendor who completed the records check;
7. Arrest, warrant and conviction data, including but not limited to:
   i. Charge(s);
   ii. Jurisdiction; and
   iii. Date.
8. Source(s) for data included in the report.

An agency must perform and document a query of an SI with the National Practitioner Data Bank (NPDB) and the List of Excluded Individuals and Entities (LEIE).
- The NPDB can be accessed at: http://www.npdb-hipdb.hrsa.gov/. Select “How to Get Started” to learn how to submit queries.
- The LEIE can be accessed at: http://oig.hhs.gov/exclusions/.

All criminal records checks conducted must be documented in writing and made part of the agency’s personnel files.

An agency that has a contract with the Department of Human Services (Department) or Oregon Health Authority for the provision of in-home care services on or after July 1, 2012 and who is subject to the Department’s criminal records check rules does not have to comply with section (12) of the rule.

For an SI hired to work or volunteer for an agency on or after July 6, 2011, an agency has until October 1, 2012 to ensure that the agency is in compliance with section (3) of the rule.
On or after July 1, 2012, an agency must ensure that a criminal records check is performed on an SI every three years from the date of the SI’s last criminal records check in accordance with the criminal background check rule.

**Violations (NEW)**

In addition to non-compliance with any law that governs an in-home care agency, it is a violation to:

1. Refuse to cooperate with an investigation or survey, including but not limited to failure to permit Division staff access to the agency, its documents or records;
2. Fail to implement an approved plan of correction;
3. Refuse or fail to comply with an order issued by the Division;
4. Refuse or fail to pay a civil penalty;
5. Fail to comply with rules governing the storage of records following the closure of an agency;
6. Fail to report suspected abuse of elderly persons as defined in ORS 124.050;
7. Fail to return a license as provided in OAR 333-536-0035; or
8. Operate without a license.

**Informal Enforcement (Updated)**

If during an investigation or survey Division staff document violations of in-home care licensing rules or laws, the Division may issue a statement of deficiencies that cites the laws or rules alleged to have been violated and the facts supporting the allegation.

An agency will be provided an opportunity to dispute the HCRQI program’s survey findings, if deficiencies are cited. If an agency desires an informal conference to dispute the survey findings, the agency shall advise the HCRQI program in writing within 10 business days after receipt of the statement of deficiencies. The written request must include a detailed explanation of why the agency believes the statement of deficiencies is incorrect.

An agency may not seek a delay of any enforcement action against it on the grounds the informal dispute resolution has not been completed.

If an agency is successful in demonstrating the deficiencies should not have been cited, the HCRQI program will reissue the statement of deficiencies, removing such deficiencies and rescinding or modifying any remedies issued for such deficiencies. The reissued statement of deficiencies shall state that it supersedes the previous statement of deficiencies and shall clearly identify the date of the superseded statement of deficiencies.

An agency must still comply with the following provision, even if it wishes to dispute survey findings:

- A signed plan of correction must be mailed to the HCRQI program within 10 business days from the date the statement of deficiencies was received by the agency. A signed plan of correction will not be used by the Division as an admission of the violations alleged in the statement of deficiencies.
- An agency shall correct all deficiencies within 60 days from the date of the exit conference, unless an extension of time is requested from the HCRQI program. A request for such an extension shall be submitted in writing and must accompany the plan of correction.

The HCRQI program must determine if a written plan of correction is acceptable. If the plan of correction is not acceptable, the HCRQI program will notify the agency owner or administrator in writing or by telephone:

1. Identifying which provisions in the plan the HCRQI program finds unacceptable;
2. Citing the reasons the HCRQI program finds the provisions unacceptable; and
3. Requesting that the plan of correction be modified and resubmitted no later than 10 working days from the date notification of non-compliance was received by the agency owner or administrator.

If the agency does not come into compliance by the date of correction reflected on the plan of correction or 60 days from the date of the exit conference, whichever is sooner, the HCRQI program may propose to deny, suspend or revoke the agency license or impose civil penalties.

**Formal Enforcement (NEW)**

If during an investigation or survey HCRQI program staff document a substantial failure to comply with in-home care licensing laws or rules, or if an agency fails to pay a civil penalty imposed under laws and rules, the HCRQI program may issue a Notice of Proposed Suspension or Notice of Proposed Revocation in accordance with ORS 183.411 through 183.470.

The HCRQI program may issue a Notice of Imposition of Civil Penalty for violations of in-home care licensing laws.

At any time the HCRQI program may issue a Notice of Emergency License Suspension under ORS 183.430(2).

If the HCRQI program revokes an agency license, the order shall specify when, if ever, the agency may reapply for a license.

The Division may reissue an agency license that has been suspended or revoked after the Division determines that compliance with these rules has been achieved.

**Civil Penalties (NEW)**

An agency that violates in-home care laws or rules, an administrative order, or settlement agreement is subject to the imposition of a civil penalty not to exceed $1,000 per violation and may not total more than $2,000.

An individual that operates an in-home care agency without a license is subject to the imposition of a civil penalty not to exceed $500 a day per violation.

In determining the amount of a civil penalty, the HCRQI program will consider whether:

1. The HCRQI program made repeated attempts to obtain compliance;
2. The licensee has a history of non-compliance with in-home care licensing laws and rules;
3. The violation poses a serious risk to the public’s health; and
4. (d) There are mitigating factors, such as a licensee’s cooperation with an investigation or actions to come into compliance.

The HCRQI program will document its consideration of the factors identified above.

Each day a violation continues is an additional violation.

A civil penalty imposed under this rule must comply with ORS 183.746.

Failure to comply with ORS 443.305 through 433.355 includes but is not limited to:

1. Failure to provide a written disclosure statement to the client or the client's representative prior to in-home care services being rendered;
2. Failure to provide the contracted in-home care services; or
3. Failure to correct deficiencies identified during a HCRQI program inspection or complaint investigation.

Questions? Contact the HCRQI program at 971-673-0540 or by email at mailbox.hclc@state.or.us