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Improving Regulatory Enforcement in the Face of Inadequate Resources

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Improving Regulatory Enforcement in the Face of Inadequate Resources

Sharona Hoffman

I. Background

In law school we often focus on the importance of carefully crafting statutory and regulatory language. Textual ambiguities or sloppiness can significantly impair the efficacy of laws and regulations. Just as important as meticulous drafting, however, is the government's ability to enforce its rules. In the absence of adequate enforcement resources, the government's regulatory initiatives may well fail. The ability to promote public welfare depends as much on regulatory compliance as it does on the text of the regulations themselves.

This exercise is designed to focus students' attention on the challenges of regulatory enforcement. It can be used in any public health law course that includes the study of regulations.

The case example is drawn from Oregon's regulation of in-home care agencies (IHCA). IHCA employees provide clients with a variety of services, such as assistance with activities of daily living, companionship, and medication reminders, but they do not furnish skilled nursing services.

Oregon has detailed and extensive statutes and regulations governing IHCAs. Oregon law provides for all of the following:

- Licensure requirements for IHCAs;
- On-site inspections by state officials every three years after initial licensure, which consist of interviews and inspection of documents, including client files, personnel records, quality improvement plans, policies, and procedures;
- Employee background checks that must be conducted every 3 years and specific offenses that disqualify individuals;
- Caregiver qualifications and training;
- Client service plans and monitoring visits by IHCA administrators;
- Complaint filing procedures and authority to investigate complaints;
- Formal and informal enforcement actions for various violations; and
- Civil penalties.¹

The content of the state's regulations, therefore, is quite strong. Yet, Oregon is disappointed with the outcome of its efforts to regulate IHCAs. Inspections generally reveal multiple violations, and many IHCAs are repeat offenders. Some do not provide caregivers with adequate training, do not prepare accurate client service plans, do not conduct monitoring visits in clients' homes, do not have proper policies and procedures, and are careless in their record-keeping. Such failures are serious because IHCAs serve vulnerable elderly and disabled clients who often cannot advocate for themselves when they receive unsatisfactory care and who may even be vulnerable to abuse.

At the root of the problem is a lack of resources. Oregon has only 2.5 full-time employees dedicated to IHCA enforcement activities, and there are 130 IHCAs. Approximately 30 of these are small opera-

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tions that serve only a handful of clients, and these are often operated by individuals who are not very sophisticated about business or legal matters.

The state's surveyors conduct thorough two-day surveys of each IHCA upon initial licensure and every three years thereafter. They prepare carefully for each

out incurring significant costs. This segment lasted approximately 30 minutes.

5. Each small group presented its recommendations, and we discussed them as a class. This segment also lasted approximately 30 minutes.

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inspection and write detailed reports after its completion. When violations are found, the surveyors require IHCAs to formulate corrective plans. However, because of time constraints, surveyors do not conduct follow-up visits to verify that remedial measures were implemented. Furthermore, although regulators have authority to impose fines for IHCA violations, they do not do so because fines trigger due process rights for offenders, including time-consuming discovery and hearings. The state has imposed fines only twice as far as anyone can remember, both times in conjunction with IHCA license revocations.

The obvious solution would be to hire more enforcement personnel. This option, however, is off the table because of budgetary constraints.

The question for students is: how can the state improve compliance without dedicating significant additional funds to IHCA regulation?

II. The Exercise

I conducted the exercise in one of my health law classes in November of 2013 and again in November of 2014. It proceeded as follows.

1. I provided students with a summary of Oregon's IHCA regulations and asked them to read it as an assignment before class. *See Appendix A.*
2. In class, we discussed Oregon's regulations, the function of IHCAs, and the regulatory challenges that the state faces, as described above.
3. After the discussion, I provided students with three slides to which they could refer as they worked in small groups. *See Appendix B.*
4. I divided students into groups of four and asked them to brainstorm and discuss ideas for improving regulatory compliance with-

III. Potential Recommendations

The following are the recommendations that I formulated for the Oregon Health Authority during my fellowship. The students thought of many of these on their own during the exercise. Instructors can discuss suggestions that were not identified by the students at the close of the session if they wish to address the topic more thoroughly.

Facilitating Compliance

1. *Ensure that websites are easy to find.* Many government agencies use websites to convey considerable information to the public, including forms and instructions relating to regulatory compliance. Some websites, however, are difficult to locate among the myriad pages run by large agencies. The government's information technology specialists should ensure that this is not the case for high-use webpages. For example, a Google search that is intuitive, such as "Oregon Health Authority in-home care" should take the user to the correct page. Furthermore, the web address should be well known to those subject to regulation and should be included on all forms and correspondence issued by the government agency.
2. *Provide extensive resource materials on the website.* Agency websites should include documents that facilitate regulatory compliance.² Resources that explain regulations, offer compliance checklists, and provide forms that are clear and not unnecessarily cumbersome are helpful. Thus, for example, websites should include frequently-asked-questions documents and interpretive guidance. Many agencies benefit from the work of student interns from local law schools and public health

schools, and such interns could be assigned to assist in developing these materials.

If the public can submit complaints to the agency, complaint forms with clear instructions should also be easily accessible on the website. Complaints can serve as a form of private monitoring and facilitate the agency's oversight work.

3. *Utilize listservs.* Government agencies can utilize listservs to educate and inform the public. Through listservs, agencies can proactively notify regulated entities of new interpretive guidelines and materials that have been added to the website or of changes in policies and procedures.
4. *Draft documents required for public distribution.* Regulated entities are often required to distribute documents, such as patient rights sheets, to clients or customers. These documents provide important information to the public and should be carefully drafted. Consequently, the drafting should be done by the government agency rather than left to the discretion of regulated entities. If the agency provides the required language, it can ensure that the documents are clear, complete, and consistent among regulated entities. Documents that must be routinely distributed by regulated entities should also be readily accessible on the agency's website.³
5. *Conduct quarterly phone conferences for regulated entities.* It is useful for agency officials to furnish opportunities for those subject to regulation to ask them questions and open a dialogue about regulatory challenges.⁴ Quarterly phone conferences or webinars can build trust and cooperation between regulators and regulated entities and convey the sense that the government is here to serve rather than to punish. A designated government official can open the event by discussing the deficiencies that have been most frequently detected during the last quarter. This discussion should be followed by a substantial question and answer period. Summaries of quarterly calls should be posted on the agency's website.

Regulated entities often express frustration, asserting that they find that regulations are difficult to interpret, the government is slow to respond to queries, and different officials provide variable and inconsistent guidance. Quarterly phone calls that are open to all regulated entities could go far to allay concerns and remove confusion.

6. *Conduct focus groups to obtain input.* Agencies can also conduct periodic focus groups with regulated entities to solicit ideas as to how compliance can be facilitated and improved. Efforts to reach out to regulated entities through phone conferences and focus groups are likely to be received enthusiastically and to generate useful input.⁵ A key to their success, however, is responsiveness. Agencies should be willing to implement changes in rules and policies if regulated entities' complaints and suggestions have merit.
7. *Provide appropriate training to enforcement personnel, including public relations training.* Many public health agencies' oversight activities include inspections and frequent contact with regulated entities. It is obvious that agencies should provide thorough substantive training to their enforcement personnel so that they are experts concerning regulatory requirements. Equally important, however, is training in the area of public relations. Maintaining a courteous and positive tone when communicating with regulated entities is a cost-free and effective tool for improving cooperation.

To this end, enforcement personnel can emphasize that they share a mission with regulated entities: providing the highest quality services to the public. Along with discussing deficiencies after inspections, surveyors should compliment regulated entities concerning things they do well. To the extent possible, agencies should cultivate a sense of partnership with regulated agencies that is devoid of resentment and hostility, while at the same time maintaining rigorous oversight and commanding respect.⁶
8. *Reexamine survey and inspection processes.* Administrative agencies that conduct surveys or inspections of regulated entities should evaluate their procedures and determine whether they can be improved. Modifications should be designed to save enforcement personnel time so that they can engage in follow-up activities that verify compliance and impose penalties where appropriate. An added advantage is that modifications may reduce the burden on regulated entities and thus foster their good will.
 - a. *Streamline inspections.* Inspections should focus initially on matters that are safety-critical for the public and need not routinely check for all possible regulatory

deficiencies. Regulated entities that are in compliance in high-priority areas could be deemed to pass the inspection without further scrutiny. Those found to have serious violations upon initial examination or those against whom complaints have been filed by members of the public should be subject to more thorough inspection.

- b. *Involve staff members of regulated entity.* A knowledgeable entity staff member should be asked to remain with the surveyor throughout the day and assist in reviewing files. Staff members can locate documents within files much more quickly than surveyors who are unfamiliar with the record-keeping system. They can also answer questions immediately and look up material that is stored electronically. Such assistance will expedite surveys and increase their accuracy. It will also prevent regulated entities from being cited for lacking documents that actually exist but have an atypical format or are not stored in the particular folder being reviewed.
- c. *Include on-site observation.* Document review alone may be insufficient to determine whether regulated entities are fulfilling their responsibilities, especially when they are serving vulnerable populations. Consequently, on-site observation and brief client interviews can be a particularly illuminating component of inspections. Although onsite observations may be somewhat time consuming, they should not be impossible to add if surveys are streamlined, as described above. Furthermore, regulated entities may welcome the opportunity to have surveyors interact with their clients and hear first-hand that their clients are happy and satisfied. Some agencies have already found observation to be an effective oversight tool. For example, the Centers for Medicare and Medicaid Services (CMS) includes home visits in its home health agency surveys.⁷

Detering Misconduct

9. *Implement strategic enforcement.* In the absence of robust enforcement resources, agencies should adopt a strategic enforcement approach.⁸ Under this model, regulators pursue the most egregious, high-end violators first (e.g., repeat offenders or those causing provable, significant harm). If penalties

that are imposed on these extreme violators are adequately publicized, they should deter similarly severe misconduct.⁹ Once the worst violations are eliminated, the government can pursue those at the next level of severity, penalize offenders, and once again deter similar wrongdoing. The goal is to eliminate acute misconduct and slowly narrow the spectrum of violations so that they generally become less serious.

10. *Use settlement agreements to minimize administrative burdens of penalty program.* It is undeniable that imposing penalties on regulated entities generates work for regulators. Penalized parties will generally have due process rights, including discovery and hearings. However, the administrative burdens imposed by penalty programs can be minimized through a simple technique: settlement agreements. Agencies can offer violators significant penalty reductions if they waive their hearing rights. Precedent for this practice has been set by CMS, which offers home health agencies a 35% penalty decrease in return for waivers of formal hearings.¹⁰ Composing settlement agreements should not be labor-intensive because these can follow a boilerplate format after initial approval by the agency's general counsel's office. At its discretion, the agency may decide in particular instances to impose fines without offering settlement agreements, such as in cases involving egregious violations or repeat offenders.
11. *Post inspection reports, penalties, and correction plans on agency website.* Public disclosures of violations and penalties, including settlement agreements, may constitute a particularly effective form of deterrence.¹¹ A 2013 study of publicly reported quality-of-care measures found that "large group practices will engage in quality improvement efforts in response to public reporting, especially when comparative performance is displayed."¹² The same will likely be true for many regulated entities.

Survey reports along with regulated entities' plans for correction should be posted on the agency's website. Here too CMS has set a precedent for the practice and enables users to search for assessments of home health agencies on its websites.¹³ Likewise, New York posts detailed quality, inspection, and enforcement information regarding its home health agencies.¹⁴ Reports concerning regu-

lated entities are often already considered public documents, but they must be specifically requested by interested parties. Posting them automatically will save agency employees time and effort because they will not need to respond to and process requests.

Regulated entities are unlikely to greet a public disclosure policy enthusiastically. If inspections occur only once every few years, entities may be very concerned about having critical reports posted as the most current information for long periods of time. A

IV. Conclusion

I was very pleased with the exercise's outcome. The exercise supplied students with an opportunity to read and think about a comprehensive set of state regulations. The students were thoughtful and creative in formulating solutions to the problem I posed and seemed to enjoy the challenge. Most students wanted to focus on punitive deterrence measures, but with a bit of encouragement, they also suggested useful ways to support IHCA's so that they could better understand the regulations and voluntarily comply with them.

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bad report may long outlive the deficiencies noted if the regulated entity quickly corrects the problems at issue. Also, citations written in technical, regulatory language may look severe to inexpert readers even though regulators recognize that they are common and relatively benign problems.

These concerns are all valid and merit serious consideration. They can be addressed in several ways. First, plans for correction should be posted along with survey reports. The text of these plans can, if appropriate, rebut objectionable deficiency findings and reassure the public that immediate and effective corrective measures will be implemented for any shortcomings that do exist. Furthermore, comparative information can put reports in perspective, allowing readers to assess each regulated entity's performance compared to that of its competitors. For example, CMS provides home health care data in three columns: the home health provider's score in various categories, the average score in the relevant state, and the national average.¹³ Finally, administrative agencies can offer informal dispute resolution mechanisms that enable regulated entities to appeal citations and have them removed from reports if their objections are meritorious.

I hope that students left the class understanding that government officials and policymakers must think as much about enforcement capacity as they do about drafting the language of the law. The very fact that regulations exist may deter some entities from engaging in misconduct regardless of how difficult compliance is or the degree to which the regulations are enforced. However, if most find compliance very burdensome and realize that violations lead to no penalties or other serious consequences, then the state's regulatory efforts may well be largely ineffectual.

APPENDIX A

"In-Home Care Agencies" Overview

- **Statute & Administrative Rules**
 - ORS 443.305 to 443.355
 - OAR 333-356-0000 to 333-356-0125
- **Definitions** (ORS 443.305 & OAR 333-536-0005)
 - "In-home care agency" means "an agency primarily engaged in providing in-home care services for compensation to an individual in that individual's place of residence." It does not include a home health agency as defined under ORS 443.005.

- “In-home care services” means “personal care services furnished by an in-home care agency or an individual under an arrangement or contract with an in-home care agency, that are necessary to assist an individual in meeting the individual’s daily needs, but does not include curative or rehabilitative services.”
- **Applicability** (ORS 443.095 & OAR 333-536-0010)
 - “No provision of ORS 443.005 to 443.105 [“in-home care agencies”] shall be construed to prevent repair or domestic services by any person.” ORS 443.095
 - ORS 443.305 through 443.355 does not apply to independent individuals, volunteers, family, neighbors, or to agencies offering only housekeeping or on-call staffing for facilities, or to support services provided or funded by the Department of Human Services. OAR 333-536-0010
 - Referral and matching services must not be licensed unless they: schedule caregivers, assign work, assign compensation rates, define working conditions, negotiate for a caregiver or client for the provision of services or place a caregiver with a client. OAR 333-536-0010
- **License requirements; application and fees** (ORS 443.315 & OAR 333-536-0021)
 - A license from the Oregon Health Authority is required.
 - Renewable annually.
 - Non-transferrable.
 - Change of ownership requires additional fees.
 - License must be conspicuously posted in an office that is viewable by the public (OAR 333-536-0021)
- **On-site inspection/surveys** (ORS 443.315 & OAR 333-536-0041)
 - The Oregon Health Authority must conduct an on-site inspection:
 - Prior to services being rendered; and
 - Once every 3 years thereafter
 - In lieu of on-site inspection, certification or accreditation certification may be accepted from a federal agency or approved authority (with conditions – see ORS 443.315(8))
 - An agency must permit Division staff access to any location from which it is operating its agency or providing services during survey. OAR 333-536-0041
- All requested documents and records must be made available to the surveyor for review and copying. OAR 333-536-0041
- A survey may include but is not limited to:
 - “Interviews of clients, client family members, agency staff management and staff;
 - On-site observations of clients and staff performance;
 - Review of documents and records;
 - Client audits.” OAR 333-536-0041
- Owner, administrator or designee is given reasonable opportunity to submit additional facts or other information to the surveyor. See OAR 333-536-0041(6)-(7)
- If deficiencies are found during the survey, the Division shall take informal or formal enforcement action. See OAR 333-536-0041 (10)
- **Classification** (OAR 333-536-0007)
 - Classifications
 - Limited — medication reminding only
 - Basic — medication reminding and medication assistance only
 - Intermediate – medication reminding, medication assistance, and medication administration only
 - Comprehensive — medication reminding, medication assistance, medication administration, and nursing services.
 - Medication services training for caregivers must be provided by a qualified individual or entity.
 - The agency may only provide services licensed to perform based upon classification.
 - The agency may not communicate (advertise, publicity, etc...) any services other than what it is licensed to perform.
- **Services provided** (OAR 333-536-0045)
 - The services must include “the safe provision of or assistance with, personal care tasks related to one or more of the following: bathing; personal grooming and hygiene; dressing; toileting and elimination; mobility and movement; nutrition/hydration and feeding; and medication reminding.”
 - In addition to personal care tasks, an agency may provide the following upon approval of the Division: non-injectable medica-

tion assistance; non-injectable medication administration; or nursing services.

- An agency may also provide housekeeping and supportive services, including but not limited to: housekeeping; laundry; shopping and errands; transportation; and arranging for medical appointments. If the client receives housekeeping and supportive services, the agency is not required to comply with all OAR provisions for those specific clients.
- Medication reminding may be provided if the client can self-direct (see OAR 333-536-005 & 333-536-0045 for conditions). The agency must evaluate whether a client can self-direct at a minimum of every 90 days. If the client can no longer self-direct, the client must be referred to an agency with the appropriate classification.
- **Organization, administration, and personnel** (OAR 333-536-0050)
 - An agency owner or designee shall assume full legal, financial, and overall responsibility for the agency's operation and serve as, or employ, a qualified administrator.
 - A qualified administrator must possess a high school diploma or equivalent; and have at least two years professional or management experience in a health-related field or program or have completed a training program approved by the Division.
 - An administrator or designee shall be responsible for the following, including but not limited to:
 - ▶ ensuring safe and appropriate services in accordance with written service plans;
 - ▶ ensuring that all personnel meet the qualification, orientation, competency, training, and education requirements in the rules;
 - ▶ ensuring that personnel assignments are consistent with the caregiver's abilities, skills, and competence;
 - ▶ ensuring the timely internal investigation of complaints, grievances, accidents, incidents, medication or treatment errors, and allegations of abuse or neglect; and
 - ▶ ensuring timely reporting of allegations of abuse to the appropriate authority.
- **Background checks; restrictions on employees convicted of certain crimes or records of**

substantiated abuse (ORS 443.004 & OAR 333-536-0010; 333-536-0093)

- "An in-home care agency shall conduct a criminal background check before hiring or contracting with an individual and before allowing an individual to volunteer or provide services on behalf of the in-home care agency, if the individual will have direct contact with a client of the in-home care agency." (ORS 443.004(2)(b))
- If an individual has been convicted of any of the following crimes listed above, the home health agency may not employ the individual. (ORS 443.004(4))
- If an individual has been convicted of any of the following, the home health agency may not employ the individual (ORS 443.004(4)):
 - ▶ Aggravated murder
 - ▶ Murder
 - ▶ Manslaughter in the first degree
 - ▶ Manslaughter in the second degree
 - ▶ Criminally negligent homicide
 - ▶ Aggravated vehicular homicide
 - ▶ Assault in the third degree
 - ▶ Assault in the second degree
 - ▶ Assault in the first degree
 - ▶ Strangulation
 - ▶ Criminal mistreatment in the second degree
 - ▶ Criminal mistreatment in the first degree
 - ▶ Kidnapping in the second degree
 - ▶ Kidnapping in the first degree
 - ▶ Subjecting a person to involuntary servitude in the second degree
 - ▶ Subjecting a person to involuntary servitude in the first degree
 - ▶ Trafficking in persons
 - ▶ Coercion
 - ▶ Public indecency
 - ▶ Private indecency
 - ▶ Child abandonment
 - ▶ Buying or selling a person under 18 year of age
 - ▶ Child neglect in the first degree
 - ▶ Possession of materials depicting sexually explicit conduct of a child in the second degree
 - ▶ Invasion of personal privacy
 - ▶ Theft in the first degree
 - ▶ Aggravated theft in the first degree
 - ▶ Organized retail theft

- ▶ Theft of services if the aggregate total value of services that are the subject of the theft is \$1,000 or more (Class C)
- ▶ Theft of services if the aggregate total value of services that are the subject of the theft is \$10,000 or more (Class B)
- ▶ Burglary in second degree
- ▶ Burglary in the first degree
- ▶ Arson in the first degree
- ▶ Computer crime (see ORS 164.377 (2) or (3))
- ▶ Robbery in the second degree
- ▶ Robbery in the first degree
- ▶ Forgery in the first degree
- ▶ Criminal possession of a forged instrument in the first degree
- ▶ Criminal possession of a forgery device
- ▶ Identity theft
- ▶ Aggravated identity theft
- ▶ Promoting prostitution
- ▶ Compelling prostitution
- ▶ Luring a minor
- ▶ Animal abuse in the first degree
- ▶ Aggravated animal abuse in the first degree
- ▶ Sex crime (see ORS 181.594)
- ▶ Delivery or manufacture of a controlled substance in the last 10 years
- ▶ Of an attempt, conspiracy or solicitation of a crime listed above
- ▶ Of a crime in another jurisdiction substantially similar to a crime listed above
- If the Department of Human Services or Oregon Health Authority has “a record of substantiated abuse committed by an employee or potential employee of a home health agency, in-home care agency, adult foster home or residential facility, regardless of whether criminal charges were filed, the department or authority shall notify, in writing, the employer and the employee or potential employee.” (ORS 443.004(7))
- If an owner or administrator has direct contact with a client, the owner or administrator must submit background information to the Public Health Division of the Oregon Health Authority. OAR 333-536-0010
- For crimes other than those identified in ORS 443.004(3), the agency must perform a weighing test (see OAR 333-536-0093 for weighing test factors).
- The background check must be nationwide. OAR 333-536-0093
- The agency must perform and document a query with the National Practitioner Data Bank (NPDB) and the List of Excluded Individuals and Entities (LEIE). OAR 333-536-0093
- **Caregiver qualifications and requirements** (OAR 333-536-0070)
 - Caregivers must be at least 18 and have sufficient communication and language skills to enable them to perform their duties and interact with clients and other agency staff.
 - Caregivers must complete agency specific orientation, conducted by the agency administrator or designee prior to providing services to clients. The orientation must include:
 - ▶ Caregivers’ duties and responsibilities;
 - ▶ Clients’ rights;
 - ▶ Ethics, including confidentiality of client information;
 - ▶ The agency’s infection control policies;
 - ▶ A description of the services provided by the agency;
 - ▶ Assignment and supervision of services;
 - ▶ Documentation of client needs and services provided;
 - ▶ The agency’s policies related to medical and non-medical emergency response;
 - ▶ The role of, and coordination with, other community service providers;
 - ▶ Information about what constitutes medication reminding and its specific limitations; and
 - ▶ Other appropriate subject matter based upon the needs of the special populations served by the agency.
 - Caregivers must complete appropriate training and have their competency evaluated and documented by the administrator or designee before independently providing services. Applicable training, includes
 - ▶ Caregivers’ duties and responsibilities;
 - ▶ Recognizing and responding to medical emergencies;
 - ▶ Dealing with adverse behaviors;
 - ▶ Nutrition and hydration, including special diets and meal preparation and service;
 - ▶ Appropriate and safe techniques in personal care tasks;
 - ▶ Methods and techniques to prevent skin breakdown, contractures, and falls;

- ▶ Hand washing and infection control;
- ▶ Body mechanics;
- ▶ Maintenance of a clean and safe environment;
- ▶ Fire safety and non-medical emergency procedures;
- ▶ Medication reminding or administration; and
- ▶ Basic non-injectable medication services.
- Caregivers with proof of current Oregon health-care related licensure or certificate are exempt from in-home caregiver training.
- Caregivers must receive a minimum of six hours of education related to caregiver duties annually. One hour of medication administration training must be required annually if the caregiver provides medication administration.
- Caregivers must be matched based upon skill, service plans must be thoroughly reviewed with each caregiver before the initial delivery of care, and caregivers must provide care based upon the service plan.
- **Medication services** (OAR 333-536-0075)
 - A registered RN must 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.
 - Agency caregivers assigned to provide medication services must be given basic non-injectable medication training before providing services and demonstrate appropriate and safe techniques. See rule for training standards.
 - An individual with a current Oregon State Board of Nursing medication aide (CMA) certification is exempt from the training requirements under OAR 333-536-0075)
- **Nursing services** (OAR 333-536-0080)
 - If an agency is approved to provide nursing services, the services must be provided by an Oregon licensed registered nurse employed by the agency and provided only to a client whose medical condition and health status is stable and predictable.
- **Service plan** (OAR 333-536-0065)
 - The administrator or designee must conduct an initial visit at the client's residence within 30 days of the initiation of services to evaluate compliance by caregivers with the service plan and to assess client's satisfaction. The initial visit must occur between the 7th and 30th day, except when the client cancels service on or before the 30th day; the client is residing in a nursing home or a hospital; or the client refuses.
 - The administrator or designee must conduct quarterly monitoring visits after the first site visit. Quarterly monitoring visits may occur by phone or other electronic means if impending discharge from services; relocation to a facility; when minimal services (one month shift) would cause the client to incur undue financial burden, or due to other circumstances justified in the chart. In no case shall the time between in-person monitoring exceed 6 months.
 - See OAR 333-536-0065 for other site visit requirements, including the caregiver being present during the monitoring visit, determining whether appropriate and safe techniques have been used.
- **Clients' rights** (OAR 333-536-0060)
 - The owner or administrator shall ensure that the agency recognizes and protects the clients' rights as set forth in OAR 333-536-0060.
 - Key rights include:
 - ▶ The right to voice grievances or complaints regarding services or any other issue without discrimination or reprisal for exercising such rights; and
 - ▶ The right to receive of a notice of the clients' right, which must include procedures for filing a grievance or complaint with the agency, the Division, and notice that the Division has the authority to examine clients' records as part of the regulation and evaluation of the agency.
- **Quality improvement** (OAR 333-536-0090)
 - Agencies must establish and maintain effective, agency wide quality assessment and performance improvement program that evaluates and monitors the quality, safety, and appropriateness of services provided by the agency, which include at a minimum:
 - ▶ Method to identify, analyze and correct adverse events;
 - ▶ 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;
 - ▶ 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.
- **Complaint filing procedures** (ORS 443.355 & OAR 333-356-0042)
 - **Reporting**
 - ▶ An employee or contract provider who has knowledge of a violation of laws or rules of the Oregon Health Authority shall use the reporting procedures established by the home health agency, in-home care agency or caregiver registry before notifying the authority or other state agency of the inappropriate care or violation, unless the employee or contract provider:
 - * “Believes a client’s health or safety is in immediate jeopardy; or
 - * Files a complaint in accordance with the rules adopted by the Oregon Health Authority.”
 - ▶ Any person may make a complaint verbally or in writing to the Public Health Division of the Oregon Health Authority. OAR 333-356-0042
 - ▶ 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 Division shall refer the matter to that agency. OAR 333-356-0042
 - **Confidentiality**
 - ▶ The information obtained by the Oregon Health Authority during an investigation of a complaint or reported violation is confidential and not subject to public disclosure.
 - ▶ Upon conclusion of the investigation, the Oregon Health Authority “may publicly release a report of its findings but may not include information in the report that could be used to identify the complainant or any client of the home health agency, in-home care agency, or caregiver registry.”
- **Investigations** (OAR 333-356-0043)
 - “An unannounced complaint investigation shall be carried out within 45 calendar days of receipt of the complaint and may include, but is not limited to:
 - ▶ Interviews of the complainant, caregivers, clients, a client’s representative, a client’s family members, witnesses, and agency management and staff;
 - ▶ On-site observations of the client(s), staff performance, client environment; and
 - ▶ Review of documents and records.”
 - If the complaint allegation represents an immediate threat to the health or safety of a client, the Division shall notify appropriate authorities and the investigation shall commence within two working days.
 - An agency must permit Division staff access during the investigation and must cooperate with all investigations of allegations of client abuse and neglect.
- **State action for injunction; operation without valid license** (ORS 443.327 & OAR 333-536-0105)
 - The Oregon Health Authority may “maintain an action in the name of the state for injunction or other process against any person to restrain or prevent the establishment, conduct, management or operation of an in-home care agency without a license.”
 - Attorney fees and court costs may be recovered.
 - If an in-home care agency is found to be operating without a valid license, it must provide notice to its clients in a manner and time set forth by the authority. It can no longer provide services to the client and must refund all fees collected for services rendered. OAR 333-536-0105
- **Grounds for denial, suspension or revocation of license** (ORS 443.325 & OAR 333-356-0033)
 - Failure to comply with in-home care agency related ORS & OAR provisions may result in denial, suspension, or revocation of license.

Noncompliance includes, but is not limited to:

- ▶ “Failure to provide a written disclosure statement to the client or the client’s representative prior to in-home care services being rendered; failure to provide the contracted in-home care services; or failure to correct deficiencies identified during an inspection by the authority.” ORS 443.325
- ▶ An owner or administrator of the in-home care agency permitting, aiding or abetting any illegal act affecting the welfare of the client. OAR 333-356-0033
- ▶ Failure to comply with ORS 443.004 – background checks. OAR 333-356-0033
- Civil penalties may be imposed as well. ORS 443.325
- **Violations** (OAR 333-536-0110)
 - “In addition non-compliance with any law that governs an in-home care agency, it is a violation to:
 - ▶ Refuse to cooperate with an investigation or survey;
 - ▶ Fail to implement an approved plan of correction;
 - ▶ Refuse or fail to comply with an order issued by the Division;
 - ▶ Refuse or fail to pay a civil penalty;
 - ▶ Fail to comply with rules governing the storage of records following the closure of an agency;
 - ▶ Fail to report suspected abuse of elderly persons as defined by ORS 124.050;
 - ▶ Fail to return a license per OAR 333-536-0035;
 - ▶ Operate without a license.”
 - **Informal enforcement** (OAR 333-536-0117)
 - During an investigation or survey, the Division may issue a statement of deficiencies and the agency has the opportunity to dispute the findings.
 - Whether the agency disputes the findings or not, the agency must mail a signed plan of correction to the Division within 10 business days from when the statement of deficiencies was received by the agency. The correction plan will not be used as an admission of the violations alleged in the statement of deficiencies.
 - Whether the agency disputes the findings or not, the agency must correct all deficiencies within 60 days from the date of the exit conference unless an extension is granted by the Division.
 - The Division may request a corrected or modified plan if it is unacceptable.
 - If the agency does not comply by the date of correction, the Division may propose to deny, suspend or revoke the agency license or impose civil penalties.
 - **Formal enforcement** (OAR 333-536-0120)
 - If the Division finds substantial failure to comply with in-home care licensing laws or rules, or if the agency fails to pay a civil penalty imposed, the Division may issue a Notice of Proposed Suspension or Notice of Proposed Revocation.
 - The Division may issue a Notice of Imposition of Civil Penalty for violations of in-home care licensing laws.
 - The Division may issue a Notice of Emergency License Suspension under ORS 183.430(2).
 - If an agency’s license is revoked, the order must specify if the agency may reapply.
 - 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** (OAR 333-536-0125)
 - A civil penalty may not exceed \$1,000 per violation and may not total more than \$2,000.
 - An individual who operates an in-home care agency without a license is subject to a civil penalty not to exceed \$500 a day per violation.
 - Factors in determining the amount of the civil penalty include:
 - ▶ The Division made repeated attempts to obtain compliance;
 - ▶ The licensee has a history of non-compliance with in-home care licensing laws and rules;
 - ▶ The violation poses a serious risk to the public’s health; and
 - ▶ There are mitigating factors, such as the licensee’s cooperation with the investigation or actions to come into compliance.
 - Each day the violation continues is an additional violation.

APPENDIX B PowerPoint Slides

OREGON IN-HOME CARE AGENCY REGS

Licensure requirements;
 On-site inspections by state officials every 3 years

- interviews of staff; review client files, personnel records, quality improvement plans, policies & procedures;

Background checks every 3 years

- long list of disqualifying offenses;

Caregiver qualifications & training requirements;
 Require client service plans & monitoring visits by IHCA administrators;
 Complaint filing procedures;
 Formal & informal enforcement + penalties

OREGON IHCA KEY FACTS

Has 128-130 IHCAs.
 About 30 very small, serving handful of clients.
 2 full-time surveyors & 1 part-time surveyor
 IHCA surveys take 2 full days
 Fines imposed only twice in recent memory, only with license revocation.
 Too burdensome b/c parties can appeal.
 IHCAs required only to formulate corrective action plans for deficiencies

- no penalties imposed for failure to develop strong corrective plans or to adhere to them.

HOW CAN REGULATORY COMPLIANCE BE IMPROVED?

Numerous violations found at each survey
 No possibility of hiring more enforcement staff or increasing resources
 Think of way to both facilitate compliance and deter misconduct

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