

COST-BENEFIT ANALYSIS

In performing a cost-benefit analysis, each rulemaking entity must provide the information requested for the cost-benefit analysis to be considered a good faith effort. The cost-benefit analysis must be submitted to the Office of Policy, Research and Regulatory Reform at least five (5) days before the administrative hearing on the proposed rule. For all questions, please attach all underlying data that supports the statements or figures stated in this cost-benefit analysis.

DEPARTMENT: Public Health and Environment

AGENCY: Health Facilities and Emergency Medical
Services Division (State Board of Health)

CCR: 6 CCR 1011-1

DATE: March 12, 2009

RULE TITLE OR SUBJECT:

Standards for Hospitals and Health Facilities, Chapter XXVI, Home Care Agencies

Benefits of the Proposed Rule(s)/Amendment(s)

1. Please provide the statutory authority, and detailed statements indicating the need for the proposed changes. *(This statement should include specific issues such as specific changes in statutes or the subject matter area, market failure, a compelling public need, risks to the health, safety or welfare of Coloradans, lack of efficient and effective performance of an important government function, or other specific problem(s) that are being addressed by the proposed rule(s).)* Please include the number of complaints you received (if any) that spurred you to take regulatory action.

The statutory authority for the proposed rule is found in Sections 25-1.5-103 and 25-27.5-101, et seq., C.R.S. Colorado was one of only five states in the country that did not license home health agencies when the legislature enacted Article 27.5 of Title 25 in 2008 mandating the licensure of home care agencies.

A home care service provides assistance to individuals and families in their place of residence in order to maintain or restore health or to minimize the effects of disability and illness including terminal illness. Services may include, but are not limited to, the following: skilled nursing care; intravenous or respiratory therapy; physical, occupational and speech therapy; wound treatment; palliative care; and assistance with durable medical equipment where installation, teaching and monitoring occur in the patient's place of residence. The provision of services can vary from intermittent half-hour visits up to continuous care for 24 hours per day, seven days per week.

Although the majority of home care consumers are age 65 and older¹, services are provided to a wide variety of recipients. Recipients include babies who have life limiting illness or disability that requires a ventilator, artificial feeding tube, or around the clock intravenous infusions to survive. Other home care recipients include growing children with physical and developmental disabilities and adults with chronic diseases such as cerebral palsy or multiple sclerosis, or disabilities such as paralysis and cognitive disorders.

The National Association for Home Care reports there are more than 25,000 home care providers caring for nearly 9 million people living with acute illness, long-term health problems, disabilities or terminal illness. This number represents a dramatic increase since 1963, when only 1,100 home care providers were in operation.² Annual expenditures for home health care are estimated to be more than \$55 billion and home health services are expected to continue to grow as the result of a shift from inpatient care to less expensive outpatient and home care along with patients' desires to be treated at home.³

¹ Home Health Care Patients: Data from the 2000 National Home and Hospice Care Survey, National Center For Health Statistics, March 2004.

² Home Health Care Industry Focus, Mary Paulsell, Associate Director, University Center for Innovation and Entrepreneurship, Columbia, MO, on the Internet at: http://www.missouribusines.net/iag/focus_home_health.asp.

³ U.S. Bureau of Labor Statistics, *Career Guide to Industries, 2008-09 Edition*, Health Care, on the Internet at <http://www.bls.gov/ovo/cg/cgs035.htm>.

The rapid growth and expanding scope of services provided in an individual's place of residence support the Colorado legislature's mandate that these services be managed through licensure to ensure the safety and welfare of the patients receiving the services.

Without state regulations, oversight of home care agencies in Colorado is limited to those agencies that are certified by the federal government to provide services paid for by the Centers for Medicaid and Medicare Services (CMS). Non-certified entities have no oversight whatsoever. Unfortunately, it is relatively easy for even the certified providers to escape scrutiny and therefore potentially endanger the health, safety or welfare of Colorado consumers. For instance, without a state license requirement, agencies that are de-certified by CMS because of serious problems can still operate by accepting private pay or non-Medicare/Medicaid patients.

Although CMS requires that home care agencies serving Medicaid or Medicare clients meet certain federal criteria, the applicable federal regulations are quite limited. The definition of a home health agency under the federal program is narrow and does not include providers of in-home infusion, respiratory therapy, personal care or nurse aide services. Similarly, there is no oversight of home infusion care and services provided to Colorado residents by pharmacies other than the basic requirement that they hold a license from the Board of Pharmacy.

The Department of Public Health and Environment is the agency designated by CMS to inspect certified home health entities on its behalf. The number of certified entities in Colorado has increased steadily in the past four years while the average number of deficiencies found by the Department has almost doubled in that same period. The number of complaints regarding certified home care agencies has risen from a total of 85 in fiscal year 2006 - 2007 to 111 for the first seven months of fiscal year 2008-2009. The severity of the complaints has also increased and tragically included the deaths of several home care consumers due to negligence, inadequate training, and lack of state enforcement capability. Examples of some of the more serious incidents are set forth below:

- A Colorado Springs agency was cited with failing to treat according to physician orders and failure to communicate with the physician. The agency staff applied a topical ointment that was not ordered by the physician to surgical pin sites on a resident's fractured ankle that caused it to become infected. The infection was not communicated to the physician and by the time the resident returned to the physician, the infection was so severe that the foot and ankle required amputation.
- An Aurora agency was cited with failing to ensure appropriate discharge planning and communication with appropriate persons. A severely depressed bi-polar resident told the agency she was losing everything including her car and home and said she therefore no longer required their services as well. The agency failed to communicate with the physician, social worker, family or adult protective services, leaving the resident alone in her depressed state. The resident was later found dead from a drug overdose.
- Two separate incidents involved failure to protect patient rights and react appropriately to an allegation of sexual molestation of a bed-bound resident. In the first incident, a Ft. Collins agency hid the allegation from the state health department who was onsite conducting another investigation. Instead of notifying the criminal authorities and suspending the accused immediately, the agency proceeded to inform the accused and place documentation in the clinical record to decrease the resident's credibility. In the second incident, an Aurora agency failed to notify the criminal authorities and failed to suspend the accused or prevent the alleged assailant from caring for other residents who were unable to communicate or protect themselves.

- An elderly resident being cared for by an Aurora agency was admitted to a hospital in an emaciated and dehydrated state with 19 decubitus ulcers, many of which were foul smelling. Documentation revealed that the resident had no wounds when she began receiving agency care activities of daily living, the agency's registered nurse assigned a CNA to visit for only 1 ½ hours a day. There was no plan regarding how the resident was to be repositioned, fed or kept clean throughout the day. There was also no plan for the CNA to provide or monitor meal or fluid intake. A comparison of medical records showed that the patient had also lost 20 pounds while in the care of the agency. The Department was unable to cite the agency as it was already under a plan of correction following prior findings of immediate jeopardy. Under CMS rules, deficient practice cannot be re-cited for similar issues that occur during an agency's period of correction.

The Department's proposed licensure requirements will provide several consumer safeguards that are not available through the federal certification process. In addition, for agencies that operate without federal certification, the proposed licensure requirements will provide the only safeguards. The proposed licensure criteria include:

- A Department determination that the agency is fit to operate the business. This involves a thorough evaluation of the license applicant's background including whether any of the applicant's other licenses or certification were limited or revoked, as well as a review of the applicant's financial resources and competence to operate the business
- Criminal background checks on owner/operators and staff.
- A requirement that agencies provide disclosure notices to consumers along with informing consumers about their respective rights.
- General licensing requirements including minimum educational, training and experience standards for the administrator and staff of an agency.
- Agency protocols that include written plans for correcting violations found on inspection and intermediate enforcement remedies as authorized by Section 25-27.5-108, C.R.S. (2008).
- A requirement to report occurrences such as death or serious injury, abuse, neglect, misappropriation of patient assets, drug diversion, and failure of medical equipment. These occurrences are investigated by the Department and may result in sanctions, including license revocation.
- Specific service requirements for home care agencies that provide skilled health services or personal care services.

2. Please list the top three benefits of the proposed regulation; explain how the proposed regulation results in the expected benefits; and if the proposed regulation reduces or eliminates the problem(s) listed above.

The top three benefits of the proposed regulations are:

- 1) The Department's ability to license and inspect all home care agencies in Colorado, along with the related oversight capability to require written plans for correcting violations found on inspection, and impose sanctions ranging from intermediate restrictions to license suspension or revocation.
- 2) The establishment of agency protocols that include reporting occurrences such as death or serious injury, abuse, neglect, misappropriation of patient assets, drug diversion, and failure of medical equipment. The Department can then investigate the reported occurrences and direct corrective action.
- 3) General licensing requirements including minimum educational, training and experience standards for the administrator and staff of an agency.

The proposed licensure regulations will result in the benefits enumerated above in the following ways. The creation of minimum standards to establish reasonable quality of care and patient safety measures that would apply to all recipients of home health services, not just Medicare and Medicaid beneficiaries. State licensure of home care agencies will also provide oversight of items that the federal certification does not cover. Agencies that either choose to be non-certified or are decertified by CMS, will no longer escape scrutiny, but be required to meet minimum state standards that will help ensure the health, safety and welfare of all Colorado home care consumers.

Agencies will also be required to proactively investigate and report certain occurrences or incidents, which will lead to better follow-up, and better outcomes for the home care consumers. If corrective actions are not implemented, the Department can then impose sanctions to either force corrective action or close an agency

whose practices endanger the public. Agencies will be required to obtain physician orders and coordinate care with health professionals when providing skilled care in order to avoid outcomes such as the example in answer to question 1 where a home care consumer's foot and ankle had to be amputated. In fact, the Department anticipates that the proposed regulations will reduce and/or eliminate many of the current problems with home care agencies delineated in answer to question 1.

3. What, in your estimation, would be the consequence of taking no action, thereby maintaining the status quo?

Section 25-27.5-104(1), C.R.S. (2008) requires the Board of Health to promulgate rules providing minimum standards for the operation of home care agencies no later than May 1, 2009. Inaction would result in violation of the legislature's statutory mandate.

4. Please describe market-based alternatives or voluntary standards that you considered in place of the proposed regulation and state the reason(s) for not selecting those alternatives. How many small businesses did you talk to about the proposed regulation?
- Market-based alternatives or voluntary standards were not considered an option because of the statutory mandate to promulgate licensing standards. Since market-based alternatives or voluntary standards are not enforceable, the Department does not consider them a viable alternative to licensure standards. Moreover, as the examples in the answer to question 1 indicate, market-based alternatives or voluntary standards have not produced a satisfactory result in reducing the number of home care agency complaints or deficiencies.

Impact of Proposed Rule(s)/Amendment(s)

5. Please describe the government costs to be incurred because of the proposed regulation (*Examples include collection; paperwork; filing; recordkeeping; audit, inspection and training costs, etc.*), and state your estimates (in dollars) of the costs that will be incurred.

These regulations will be used for the purpose of establishing standards for the provision of skilled medical care and/or personal care to consumers in their home or place of residence and determining whether an applicant should be issued a license to operate a Home Care Agency (HCA) in Colorado.

Licensure involves:

- Review of the licensure application and supporting materials,
- Providing technical assistance to applicants/licensees regarding processes and requirements,
- Evaluating the applicant/licensee's compliance history in Colorado and/or other states,
- Reviewing the results of a criminal history background check for the licensee,
- Conducting on-site and/or off-site inspections that include reviewing HCA policies and procedures, interviewing HCA clients and staff, reviewing HCA patient records, and/or other compliance verification as determined by the Department,
- Citing HCA's for instances of deficient practice found during inspections,
- Reviewing plans of correction, and conducting revisits as needed to verify corrections have been implemented.

Licensure also involves, on an as-received basis, investigating complaints and following up on occurrence reports. Complaint investigation includes in-take of information, assessment of the severity of the allegations and whether the department has jurisdiction in the matter, and investigation and resolution as described above under inspections. Occurrence report follow-up includes in-take of information, assessment of the severity of the incident, determining that all required information has been reported, and verifying that the licensee has taken appropriate action to prevent further incidents.

Costs include direct costs for staff time to carry-out the activities described above, general office operations and supplies, and travel expenses related to on-site inspections and investigations, and indirect costs distributed by the Department for building lease, utilities, etc.

Total annual Department costs to implement HCA licensure are estimated at \$524,000.

6. Please provide the number and types of entities or small businesses that will be required to comply with the proposed rule(s). Please provide the source of data used (*i.e., program data, NAICS code statistics, etc.*).

There are currently 143 certified home care agencies that provide skilled medical services and 158 certified home care agencies that provide personal care services, with some agencies providing both types of services. The Department is aware of this number because it is the agency charged with performing inspections of these entities on behalf of CMS. The Department estimates that there are an additional 92 home care agencies providing skilled medical services and 200 providing personal care services that are uncertified or private pay. The Department's estimates are based upon information from various trade groups, agency associations and other health care providers.

7. Does the proposed regulation create barriers to entry (*i.e., licensing, permit or educational requirements*)? If so, please describe those barriers and why those barriers are necessary.

The proposed regulations and the enabling statute specify all home care agencies operating in Colorado must be licensed as of January 1, 2011. Since the proposed regulation applies to all home care agencies regardless of size or type, it is not perceived as creating any barriers to entry.

8. Explain the additional requirements with which small business owners will have to comply (*i.e., will they need to purchase new equipment or software to meet the requirement(s); are there training costs; are there new disclosure/filing requirements they will have to provide to the state; are there transactional costs, paperwork costs, recordkeeping, etc.*). Please state your estimates (in dollars) of the compliance costs by types listed. Please state your estimates (in dollars) of the compliance costs by types listed. A cost benefit analysis is required for the following: 1) The timelines for providing information to the Department proposed in rules 5.5(B)(1) and (B)(2) as well as clarification on the frequency of inspections and if agencies will be subject to a renewal inspection each year and the costs associated with renewal inspections; 2) Education, reporting, recordkeeping and inspection requirements that are duplicative of, or more stringent than, existing regulations of other federal or state regulatory bodies; and 3) With regard to rule 5.2, clarifying the purpose for the information required on renewal applications and the costs associated with providing that information.

1) Rule 5.5 (B)(1) and (B)(2) states: "The Department shall investigate and review each initial and renewal license application in order to determine an applicant's compliance with this Chapter. The determination shall be based on one or more of the following: (1) An on-site investigation of the agency; (2) a review of the application and associated documents." The timelines for submission of an initial license application by an existing home care agency are mandated by statute at Section 25-27.5-103, C.R.S. An agency that provides skilled home health services shall submit a completed license application by June 1, 2009, and an agency that provides in-home personal care services shall submit a completed application by January 1, 2010. An agency's cost to comply with those deadlines and submit the requisite information will presumably vary according to the size and sophistication of the agency. The Department will offer agencies the opportunity to fill out the application through an electronic process, thereby saving material and copying costs. The information required should be readily available to the agency such as the name and address of the agency and respective owners, the type of services provided, the most recent workers' compensation audit or similar documentation to establish the agency's license fee tier, and proof of liability insurance. These same requirements apply to all health facilities licensed by the Department.

Once the Department receives an initial application, it anticipates completing a preliminary review within 30-45 days. If the Department determines that the information submitted is incomplete, it will not summarily reject the application, but will coordinate with the agency in question to obtain whatever else is needed. With regard to license renewals, the application process will be even more streamlined resulting in significant cost savings because the information submitted with the initial application will be electronically saved and will not have to be re-entered by an agency unless that information has changed. The Department anticipates that it may take an agency two hours at the most to complete an electronic renewal application.

Due to stakeholder input, the licensing fee schedule was significantly reworked and the proposed fee structure is based upon what providers believed they could afford in these difficult economic times. In response to the reduced fees, the Department plans to assure agency compliance with licensing criteria

using the variety of measures listed in rule 5.5 (B). The Department also anticipates performing routine onsite investigations every two to three years, not every year upon renewal. The estimated cost for an agency to prepare for and participate in these onsite inspections will on again vary depending upon the size and organizational structure of the agency. Onsite investigations typically last anywhere from one to five days, depending upon the size of the agency and the results of the investigation. One staff person is generally made available by the agency to assist the Department representative with locating and copying records. No staff members are required to accompany the Department representative when visiting and interviewing the home care agency's consumers. Additionally, although the Department initially considered a separate survey fee for routine on-site inspections, the idea was discarded in response to stakeholder input. Finally, it should be noted that survey frequency will be largely driven by complaints and compliance history. Well-performing agencies will thus be able to limit the frequency and duration of surveys, thereby limited their associated costs.

2) If provided by a nationally accredited or federally certified agency, information regarding education, reporting, recordkeeping and inspections requirements will be considered by the Department as set forth in Rule 5.5(B). However, the Department retains the discretion to request any additional documentation it deems necessary to assure an agency's compliance with the licensing criteria. As pointed out by the examples used in answer to Question 1, federal certification does not always ensure adequate care to consumers or good agency operation. Additional documentation, if requested by the Department, should not impose an undue burden on a well-organized and well-run agency. The proposed fee for a license renewal is the same as the proposed fee for an initial license and, as previously mentioned, there should be significant cost savings associated with the electronic renewal application process. With regard to on-site inspections, the Department intends to combine on-site licensure inspections with CMS certification inspections whenever possible.

The staff time required to comply with the additional education, reporting and recordkeeping requirements will, again, depend on the size and type of agency. Federally certified agencies are already required to meet certain educational requirements. Certified Nurse Aides (CNAs) are already required to complete 12 clock hours of initial training plus ongoing in-service training. The on-going training requirement for direct care staff with a federally certified skilled home care agency can easily be met with a once a month staff meeting. The educational and training requirements are consistent with those required for similar positions in other health facilities. For example, an administrator for an assisted living residence must document 30 actual hours of training or related experience before commencing work in that position and an administrator for a long-term care facility must be separately licensed by the Department of Regulatory Agencies in order to assure quality administration and sound management of nursing homes to provide nursing home residents a measure of protection.

With regard to reporting and recordkeeping requirements, any home care agency with a good business model should already have in place processes for reporting and recordkeeping for its own protection as well as that of the consumer. The primary reporting requirement contained in the proposed rules concerns the agency's duty to report occurrences which is required of all licensed health facilities pursuant to Section 25-1-123(2), C.R.S. Therefore, the Department believes that the staff time involved in complying with any additional education, reporting and recordkeeping requirements will be minimal and not impose an undue burden on licensed home care agencies.

3) A completed application will be required for each license renewal. However, as previously outlined, the electronic application process will essentially only require information updates resulting in less preparation time for the agency. The background check required for *each* agency owner, applicant or licensee as set forth in rule 5.2(D) will only need to be done once unless there is a change in that ownership structure. This background check is mandated by Section 25-27.5-106, C.R.S. and the cost, payable to the Colorado Bureau of Investigation, is \$39.50 per individual. The criminal background check for agency employees is mandated by Section 25-27.5-107, C.R.S. and applies only to persons seeking employment with an agency after June 1, 2009. The statute and rules specify that either the agency *or* the person seeking employment shall pay for the cost of that background check. Once a background check on a potential employee is satisfactorily completed, the agency does not need to repeat it every year unless they so choose.

9. Please state whether the proposed regulation contains different requirements for different sized entities or different geographic regions, and explain why this is, or is not, necessary. *(For example, an audit fee (as a percentage of assets) for a bank examination is lower based upon a higher level of assets due to marginal cost savings and water usage is more restricted in geographic regions with less water storage or supplies because demand far outpaces supply.)*

The requirements for agencies that provide skilled medical services are more stringent than the requirements for agencies that provide only personal care services because of the requisite skill necessary to provide skilled medical services versus homemaker or companion services. The only other distinction between different sized entities or geographic regions is in the license fee schedule. In response to stakeholder request, fees were tiered to hold down costs for rural or small agencies.

10. Please describe your understanding of the ability of small business owners to implement changes required by the proposed regulation, and state the average estimated cost of implementation. *(For example, if a proposed rule required all business in a particular sector to utilize a specific software application, a small business owner may have a difficult time implementing the software if the software is expensive to purchase or if their existing computers are not able to run the software.)*

As stated in the answer to question 9, the Department tiered the license fee schedule to hold down costs for rural or small agencies.

11. Please state if the proposed regulation will force the cessation of business by any existing businesses, and the impact the cessation will have on the economy including but not limited to the number of employees losing their jobs, the economic losses by the businesses and the estimated economic ripple the cessation will have on suppliers, consumers or buyers.

Since sharing the final proposed fee schedule, the Department has not received any information that these regulations would cause any agency closures.

12. Does the proposed regulation restrict consumer choice *(i.e., availability of goods or services; price increases; etc.)*? If so, please describe those restrictions.

Since the proposed regulations will apply to all home care agencies regardless of location or size, there should be no impact on consumer choice.

13. Please state the estimated impact (in dollars) the proposed regulation will have on sales, employment or tax revenue.

There is no anticipated monetary impact of the proposed regulation on sales, employment or tax revenue

14. Please identify all other small business sector(s) that the proposed regulation(s) may impact, and state the estimated financial impact the proposed regulation will have on each small business sector.

As mandated by statute, the proposed regulations will also require that home care placement agencies register with the Department, perform background checks on the personnel they intent to place, and provide disclosure notices to the consumers with whom they place personnel. The Department is unaware of any other small businesses that the proposed regulations would impact.