DIVISION OF PUBLIC & BEHAVIORAL HEALTH
BUREAU OF HEALTH CARE QUALITY AND COMPLIANCE
Medical Facilities and Other Related Entities
LCB File No. R109-18

Informational Statement per NRS 233B.066

1. A clear and concise explanation of the need for the adopted regulation;

The purpose of the amendment is to bring Nevada Administrative Code (NAC) Chapter 449 into compliance with Nevada Revised Statutes (NRS) 449.03005(2), NRS 449.0304, and NRS 449.165(5). These are new statutes that were passed during the 2017 legislative session and require the Board of Health to adopt regulations to carry out the provisions of the statutes.

NRS 449.03005 (2) requires the Board of Health to adopt:

- Standards for licensing of employment agencies that provide nonmedical services related to personal care to elderly persons or persons with disabilities in the home;
- Standards relating to the fees charged by such employment agencies;
- Regulations governing the licensing of such employment agencies; and
- Regulations establishing requirements for training the persons who contract with such employment agencies to provide such nonmedical services.

NRS 449.0304 & NRS 449.4309 requires the Board of Health to adopt regulations authorizing an employee of a residential facility for groups, an agency to provide personal care services in the home or a facility for the care of adults during the day (NRS 449.0304) or an intermediary service organization (NRS 449.4309), with the consent of the person receiving services, to:

- Check, record and report the temperature, blood pressure, apical or radial pulse, respiration or oxygen saturation of a person receiving services from the facility or agency;
- Use an auto-injection device approved by the Food and Drug Administration for use in the home, administer to a person receiving services from the facility or agency insulin furnished by a registered pharmacist as directed by a physician or assist such a person with the self-administration of such insulin; and
- Use a device for monitoring blood glucose approved by the Food and Drug Administration for use in the home, conduct a blood glucose test on a person receiving services from the facility or agency or assist such a person to conduct a blood glucose test on himself or herself.

The regulations adopted:

- Must require the tasks described in subsection 1 to be performed in conformance with the Clinical Laboratory Improvement Amendments of 1988, Public Law No. 100-578, 42 U.S.C. § 263a, if applicable, and any other applicable federal law or regulation;
- Must prohibit the use of a device for monitoring blood glucose on more than one person; and
- May require a person to receive training before performing any task described in subsection 1.

NRS 449.165 (5) requires the Board of Health to establish an administrative penalty to be imposed if a violation by a medical facility, facility for the dependent or a facility which is required by the regulations adopted by the Board pursuant to NRS 449.0303 to be licensed causes harm or the risk of harm to more than one person.

2. A description of how public comment was solicited, a summary of public response, and an explanation how other interested persons may obtain a copy of the summary;

Public Workshop - March 6, 2018
A public workshop was held on the proposed regulations at the Division of Public and Behavioral Health located at 4150 Technology Way in Carson City and it was video conferenced to Southern Nevada Health District, 280 S. Decatur Blvd, in Las Vegas.

Thirty-four (34) individuals signed the sign-in sheet in the Carson City location, three signing in support, nine people signing in support and/or opposition of portions of the proposed regulations, one individual noted "Amend" and the remaining individuals on the sign in sheet did not indicate their position.

Fifty-four (54) individuals signed the sign-in sheet in the Las Vegas location, with one person signing in support, one person signing in opposition, three individuals signing in support and/or opposition of portions of the proposed regulations, and the remaining individuals on the sign in sheet not indicating their position.

Below is a high-level summary of the testimony provided during the public workshop. Please refer to the attached written testimonies for more in-depth details on the testimony provided during the public workshop.

- Definition of a hospital unit should be based on acuity of care and the current definition in NRS is too broad. Others expressed agreement with how a hospital unit is currently defined.
- There is no description as to how the star ratings should be posted.
- Concerns that the proposed regulations relating to employment agencies that provide nonmedical services related to personal care to elderly persons or persons with disabilities in the home don't require individuals to be background checked or require training. Out-of-state employment agencies and internet-based employment agencies that do business in Nevada were also mentioned.
- Glucose testing and vital signs are exempt from CLIA.
- Concerns were expressed relating to the increase in monetary penalties. It was expressed that sanction guidelines should be in place to support improvement and not close facilities. There was also concern that the monetary penalties were disproportionate and an extreme hardship for residential facilities for groups when compared to a facility like a hospital. That there should be different level of fines for residential facilities for groups. It was also mentioned that severity and scope are not mentioned in the proposed regulations.
- IDR (informal dispute resolutions) process should be allowed.

- SLA's (Supported Living Arrangements) and CBLA's (Community Based Living Arrangements) should be licensed under the same provisions (NAC Chapter 449)).

Industry Advisory Groups
The proposed regulations were also presented to the adult day care advisory council on August 23, 2018, the personal care agencies advisory council on March 13, 2018 and September 11, 2018, and the assisted living advisory council on January 25, 2018 and October 18, 2018. Feedback from the advisory groups was also taken into consideration when developing the proposed regulations. Two recommendations for changes to the proposed regulations from the October 18, 2018, assisted living advisory council meeting included:

- Pharmacists should be allowed to train caregivers on insulin autoinjection devices and glucose monitoring testing.
- Monetary penalties should be applied on a factor commensurate with the rate of pay for a residential facility group. It was suggested that residential facilities for groups pay 20% of each sanction amount listed in the proposed regulations.

Public Hearing - December 7, 2018:
One individual testified in support of the changes related to NRS 449.03005, NRS 449.0304, and NRS 449.4309. She noted they help keep people safe. She noted being able to perform vital signs helps save money and appreciates how the changes are written. She gave her thanks.

One individual representing the Nevada Assisted Living Association noted support for the changes made as a result of SB 324 (of the 2017 legislative session) with the amendments related to pharmacists. She noted that the changes made as a result of SB 71 (of the 2017 legislative session) were not acceptable and needed to allow for differences between non-medical type facilities with a lower pay rate compared to medical type facilities. She noted there are different levels of care and the penalties should be related to the different levels of care. She also noted a directed plan of correction should be utilized before administering monetary penalties. She also noted residential facilities for groups do not have the option for an informal dispute resolution.

Another individual, a member of the Association of Homecare Owners of Northern Nevada, had similar concerns, noting penalties ranging from 250% to 500% will have a severe impact on the already financially beleaguered homecare industry. She also noted that consideration of how the regulators do their part in the implementation of NRS 449 would need to be looked into; that homecare owners needed a written, formalized independent dispute resolution process like skilled nursing facilities; and noted that imposing higher penalties is not the solution to the challenging issues faced by the Bureau. Please see attached written testimony for full details.

A Board of Health member requested the Division representative provide a response to the testimony provided.

The following response was provided by the Division representatives:

The regulation does increase monetary penalties, but the amount of the penalties in regulations have not increased since 2002. The Division has mitigated these increases with section 17 that allow a facility to use the fines to correct deficiencies and improve their facilities in lieu of paying the penalty thus reinvesting that money back into their facilities for a first violation.

It was also noted that NAC 449.99904 allows a facility that waives the right to a hearing, corrects the deficiencies, and pays the monetary penalty within 15 days, after receipt of the notice of the penalty, to receive a 25 percent reduction in the penalty.

It was also noted that while the changes to the fines established represent increases, the legislation driving these changes was generated by the Division during the 2017 legislative session and significantly reduced the maximum fines to a reasonable amount. It was noted that if you look at SB 71 it repealed the statute that set a total monetary penalty of not less than $1,000 and not more than $10,000 for each patient who was harmed or at risk of harm. An example was provided that if a residential facility had 5 residents and each resident had a violation which resulted in harm or the risk of harm, such as at a severity level 4, a fine of $10,000 could be assessed for each resident resulting in a fine of $50,000. The statutes were also revised to increase the current imposition of an administrative penalty of not more than $1,000 per day for each violation to not more than $5,000 per day for each violation. Although the statutes allow for a per day monetary penalty for each violation the Division rarely applies per day violations. Most sanctions are imposed on a per deficiency basis and not daily. In addition, although the statutes allow for the imposition of interest, interest is rarely, if ever imposed.

The residential facilities for groups industry requested that smaller facilities be charged smaller amounts, for example, 20% of the proposed sanction amounts. One example was given of what this would look like:

A facility has a severity level 4 violation which resulted in the death of a resident (one resident) due to the facility's violation. Per the adopted regulations, for initial deficiencies of a severity level of four that creates harm or risk of harm to one person, an initial monetary penalty of $2,500 per deficiency must be imposed. The current regulations (not the adopted one) would result in a $1000 penalty in this case. If this was reduced so a residential facility for groups only had to pay 20% it would result in a fine of $500 (less than what is currently required) and if the facility met the requirements for the 25% reduction allowed in current regulations, this violation that resulted in a death (or serious harm) would result in a $125 fine.

The Division believes that the intent of passage of the SB 71 of the 2017 legislative session was not to reduce fines but to remove the extremely high-level fines that were in the statutes and replace it with higher fines than currently assessed at reasonable levels.

In addition, based on historical data, only 2% to 4% of all facilities receive state monetary penalties, so very few facilities should be impacted. Those that are affected will have violated regulations resulting in serious harm or risk of harm to patients/residents. The Bureau has not historically seen facilities go out of business based on fines. In fact, data shows that severity level three or four violations that result in monetary penalties have decreased since 2015.

Of note, although not provided in testimony, the Bureau does have an informal dispute resolution/administrative review policy. CMS certified facilities (skilled nursing facilities, intermediate care facilities and home health agencies) may submit a federal informal dispute resolution (IDR) and state licensed only facilities may submit an administrative review, both of which allow a facility to submit to the Bureau documents disputing specific findings with evidence which identifies why the Bureau's finding was in error. If the facility submits the IDR or administrative review in accordance with the Bureau's policy, the evidence will be reviewed, and a determination of the review will be provided to the facility.

The public workshop notice with information on how to obtain a copy of the proposed regulations and small business impact statement was posted on the LCB website on February 7, 2018 and distributed to NAC Chapter 449 licensed health facilities on February 7, 2018.

The public hearing notice with information on how to obtain a copy of the proposed regulations and small business impact statement was posted on the LCB website on 10/18/18 and distributed to NAC Chapter 449 licensed health facilities by October 10/18/2018 with a revision of the errata sent to NAC Chapter 449 licensed health facilities on November 1, 2018. The public hearing notice was sent out with information on how to obtain the first LCB draft of revised proposed regulations R109-18 and errata, with a revised errata being sent out on November 1, 2018, as previously mentioned. On November 9, 2018 LCB issued the second revised draft, LCB draft of second revised proposed regulations R109-18. This version incorporated the information on the errata except it did not include the portion in the errata related to allowing pharmacists to conduct caregiver trainings related to the use of insulin autoinjection devices and waived glucose monitoring.

<u>How other interested persons may obtain a copy of the summary</u>

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Leticia Metherell, RN, CPM, HPM III at the Division of Public and Behavioral Health at:

Division of Public and Behavioral Health
Bureau of Health Care Quality and Compliance
727 Fairview Drive, Suite E
Carson City, NV 89701
Leticia Metherell

Phone: 775-684-1045
Email: lmetherell@health.nv.gov

3. A statement indicating the number of persons who attended each hearing, testified at each hearing, and submitted written statements regarding the adopted regulation. This statement should include for each person identified pursuant to this section that testified and/or provided written statements at each hearing regarding the adopted regulation, the following information, if provided to the agency conducting the hearing:
   (a) Name
   (b) Telephone Number
   (c) Business Address
   (d) Business telephone number
   (e) Electronic mail address; and
   (f) Name of entity or organization represented

A public hearing was held on December 7, 2018. Although 36 individuals signed in at the Carson City location and 55 individuals signed in at the Las Vegas location, there were other items on the Board of Health agenda, for which individuals may have been attending. For a summary of the testimony provided please refer to number 2. For the list of attendees, please refer to the Carson City and Las Vegas public hearing attendance sign-in sheets included with this informational statement.

4. A description of how comment was solicited (i.e., notices) from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary.

The Division of Public and Behavioral Health (Division) has requested input from Nevada's licensed health care facilities and has made a concerted effort to determine whether the proposed regulations are likely to impose an economic burden upon a small business.

All licensed health facilities were sent an email notification on November 21, 2017 (an updated email was also sent on November 27, 2017 with an updated web link to the small business impact questionnaire), requesting that all interested individuals complete the small business impact questionnaire. A link to the small business impact questionnaire and proposed regulations was provided. The proposed regulations were also posted on Division's website. The questions on the questionnaire were:

1) How many employees are currently employed by your business?
2) Will a specific regulation have an adverse economic effect upon your business?
3) Will the regulation(s) have any beneficial effect upon your business?
4) Do you anticipate any indirect adverse effects upon your business?
5) Do you anticipate any indirect beneficial effects upon your business?

Summary of Response

Summary of Comments Received (115 responses were received out of 1,406 small business impact questionnaires distributed)			
Will a specific regulation have an adverse economic effect upon your business?	**Will the regulation (s) have any beneficial effect upon your business?**	**Do you anticipate any indirect adverse effects upon your business?**	**Do you anticipate any indirect beneficial effects upon your business?**
Yes- 114 No - 1	Yes - 6 No- 107 No Answer - 2	Yes - 112 No – 1 No Answer - 2	Yes - 2 No – 112 No Answer – 1

Below is a high-level summary of the comments received from the small business impact questionnaire. For a more detailed account of the comments received (includes breakdown by questions) please see Attachment 1.

Most respondents indicated that the proposed regulations would have an adverse economic effect upon their business and would not have any beneficial effect including:

- Increased monetary penalties placing a significant economic burden on facilities, severely impacting industry, leading to increased costs for residents and resulting in a higher burden on smaller facilities than larger ones with more resources.
- Adversely impacting businesses that receive a low star rating.
- Concerns that HCQC did not fully enact the bills as intended.
- Concerns with the costs associated with obtaining a CLIA waiver and that liability insurer premiums will go up substantially if a facility has a laboratory designation.
- Increased costs and staff time to carry out new training requirements.
- Increased costs related to posting star rating information and increased cost to maintain a daily staffing committee.

A minority of respondents felt the proposed regulations may have a beneficial effect upon their business including:

- Enhanced care outcomes through coordination of information on vital signs with physicians and related health care providers.
- Less expense to taxpayers by reducing reliance on ambulance services.
- Reduced costs to diabetic clients who will be able to be placed in a residential care type facility instead of a higher cost nursing facility.
- Enhanced quality of care to individuals in long term care facilities who rely on personal

care attendants because they would be required to be licensed in accordance with 449 regulations.

How other interested persons may obtain a copy of the summary

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Leticia Metherell, RN, CPM, HPM III at the Division of Public and Behavioral Health at:

Division of Public and Behavioral Health
Bureau of Health Care Quality and Compliance
727 Fairview Drive, Suite E
Carson City, NV 89701
Leticia Metherell
Phone: 775-684-1045
Email: lmetherell@health.nv.gov

5. If, after consideration of public comment, the regulation was adopted without changing any part of the adopted regulation, a summary of the reasons for adopting the regulation without change. The statement should also explain the reasons for making any changes to the regulation as adopted.

The Division made several revisions to the proposed regulation based on industry feedback.

Pharmacists were added to the errata allowing them to train caregivers on insulin autoinjection devices and glucose monitoring testing.

The concerns that the originally proposed monetary sanctions were too high, were disproportionate when comparing smaller facilities to larger facilities, and should be in place to support improvement were all considered when developing the proposed regulation. A provision was added to the proposed regulations which authorizes a facility to request to use all or a portion of an initial monetary penalty to correct the deficiency for which the penalty was imposed in lieu of paying the penalty and authorizes the Bureau of Health Care Quality and Compliance of the Division to approve such a request if the deficiency results from the facility's first violation of a particular provision of law or regulation. In addition, the initial monetary penalties imposed if a violation creates harm or risk of harm to one person or which would be assessed if the violation creates harm or risk of harm to more than one person were reduced from the originally proposed amounts for severity level three or four violations. The severity level of two and scope level of three violation remained unchanged from the originally proposed amounts as the payment of this monetary penalty must be suspended if the facility has corrected the deficiencies within the time specified in the plan of correction approved by the Bureau. Based

on data from past monetary penalties, 2% to 4% of all licensed health facilities are anticipated to be affected by monetary penalties. The recommendation to charge residential facilities for groups to only 20% of an assessed monetary penalty was not moved forward in the proposed regulations. There have been arguments that smaller facilities make less and should pay less in fines, but there have also been arguments that larger facilities have more opportunities to fail because they care for more residents, so fines should be risk adjusted. The proposed regulations set a standard set of fines that are based on a graduated scale based on harm to patients/residents. In addition, the revisions made allow all facilities that receive a monetary penalty to reinvest the initial monetary penalties back into their facilities in lieu of payment to correct deficiencies for first violations; therefore, supporting improvements which hopefully will result in fewer to no repeat deficiencies. In the end, it was felt that the combination of allowing facilities to reinvest initial monetary penalties into their facilities to fix initial violations, a scaled approach to monetary penalties based on harm, and the fact that a small percentage of facilities receive monetary penalties, was the best approach to ensure the public's safety when residents are harmed while at the same time allowing the use of monetary penalties to support improvements, rather than having different levels of monetary penalties based on reasons other than harm caused to patient/residents.

NRS 449.0304 and NRS 449.4309 (2)(a) note: "The regulations adopted pursuant to this section: (a) Must require the tasks described in subsection 1 to be performed in conformance with the Clinical Laboratory Improvement Amendments of 1988, Public Law No. 100-578, 42 U.S.C. § 263a, if applicable, and any other applicable federal law or regulation;" The tasks in subsection 1 includes using a device for monitoring blood glucose, performing a blood glucose test on a person receiving services from the facility or agency or assisting such a person to conduct a blood glucose test on himself or herself. The Centers for Medicare and Medicaid Services (CMS), Clinical Laboratory Improvement Amendments (CLIA) section of Region 9, which includes Nevada, was consulted. CMS provided the following information: If the patients are performing the waived glucose testing on themselves, CLIA certification would not be required. However, if the facility is performing the waived glucose testing on its residents, regardless of whether the glucometer has been approved from home use, CLIA certification would be required.

The proposed regulations were revised based on its analysis to minimize impact by only requiring conformance with CLIA when required, as applicable, by state and federal law. The proposed regulations do not require additional state licensing requirements or conformance with CLIA when it is not required.

The Division revised the proposed regulations based on industry feedback and removed the requirement in Section 22 (NAC 449.2726) which requires the resident's medication be administered by a medical professional, or licensed practical nurse who is not employed by the residential facility; therefore, allowing medical professionals and licensed practical nurses employed by the facility to administer a resident's medication. It would be up to each medical professional and licensed practical nurse to ensure he or she follows the scope of practice outlined by his or her occupational licensing board when administering medications.

It was also requested that an allowance to perform weights be added, which was done.

The Division did revise section 12 of the proposed regulations to outline the size, font and other characteristics of the Centers for Medicare and Medicaid Services (CMS) star rating posting required by NRS 449.1825 and clarified that each entrance to the facility means to each entrance to a building where activity is conducted for which a license as a medical facility or facility for the dependent is required. Section 12 currently does not apply to facilities for the dependent as CMS currently does not assign star ratings to these facility types.

The proposed regulations relating to employment agencies that provide nonmedical services related to personal care to elderly persons or persons with disabilities do not address background check requirements because this was included in the law, so the NRS Chapter 449 and NAC Chapter 449 background check requirements, would apply to this facility type. The proposed regulations were revised so that the attendant training required for this facility type are similar to the training required for personal care agencies. Out-of-state employment agencies and internet-based employment agencies that do business in Nevada were not added in the proposed regulations as the statutory definition would dictate whether an agency is required to be licensed or not.

The following revisions were not made to the proposed regulations:

Requiring Supported Living Arrangement Services (SLA) and Community Based Living Arrangements (CBLA) to follow NAC Chapter 449 regulations was not implemented because SLA's and CBLA's are not governed by NRS or NAC Chapter 449; therefore, the proposed regulations do not apply to these two facility types. CBLA oversight is conducted in accordance with NRS/NAC Chapter 433 and SLA oversight is conducted in accordance with NRS/NAC Chapter 435.

The proposed regulations were not changed to allow all facilities to request an informal dispute resolution (IDR) because the Bureau offers different methods a facility can dispute and/or provide further evidence of compliance when there is a disagreement with a Bureau's findings. When monetary penalties are assessed the Bureau allows for a prehearing in which the facility may present further evidence of compliance and which may result in a resolution agreeable to both the facility and the Bureau without going to hearing. If an agreement is not achieved, the facility may pursue a hearing.

CMS certified facilities (skilled nursing facilities, intermediate care facilities and home health agencies) may submit a federal informal dispute resolution (IDR) and state licensed only facilities may submit an administrative review, both of which allow a facility to submit to the Bureau documents disputing specific findings with evidence which identifies why the Bureau's finding was in error. If the facility submits the IDR or administrative review in accordance with the Bureau's policy, the evidence will be reviewed, and a determination of the review will be provided to the facility.

The definition of "Unit" was not changed in the proposed regulations because "Unit" is defined in statutes, NRS 449.2418; therefore, no changes to this definition can be made in regulations.

6. The estimated economic effect of the regulation on the business which it is to regulate and on the public. These must be stated separately, and in each case must include:
   (a) Both adverse and beneficial effects; and
   (b) Both immediate and long-term effects.

Anticipated effects on the businesses which NAC 449 regulates:

Adverse effects: It will have an adverse economic effect on facilities that receive a monetary penalty although it is anticipated only a small percentage (2% to 4%) of facilities would be impacted. The following information is based on all health facilities that have received at least one severity 3 or 4 citation over a one-year period. Based on this information, 4% of health facilities received at least one severity level 3 or 4 citation in 2015, 3% in 2016 and only 2% in 2017. This decline in the percentage of health facilities receiving at least one deficiency at a severity 3 or 4 should alleviate concerns expressed by industry that inconsistencies in how regulations are interpreted by inspectors may lead to an increase in monetary penalties. It is possible that of the small percentage of facilities that receive a severity level 3 or 4, some may have difficulties paying or using the monetary penalties to correct violations resulting in a negative impact on their business.

Beneficial effects: The proposed regulations may result in financial benefits to certain industry by removing the requirement that a resident's glucose testing be performed by a medical laboratory licensed pursuant to chapter 652 of NRS; therefore, eliminating licensure as a laboratory with all the associated fees and state specific requirements to serve as a director of a laboratory. Benefits to the public include adding training requirements to perform certain tasks and utilizing nationally recognized infection control guidelines when carry out such tasks, to help ensure these activities are carried out in a safe and effective manner. Industry that previously may not have been able to accept certain residents/clients requiring the care noted in the direct beneficial effects section may now be able to do so, potentially increasing the number of residents they can accept, or allowing residents/clients that may have needed to be transferred to a higher level of care to remain at the facility.

Immediate effects: The adverse effects may be immediate, upon passage of the proposed regulations, for those that receive a monetary penalty shortly after the passage of the proposed regulations. Upon passage of the proposed regulations, certain facilities will be able to immediately begin performing the tasks noted previously, after certain criteria are met, such as performing glucose testing using a glucometer and vital signs in their facilities, possibly allowing them to admit additional resident/clients they were not able to in the past or retain residents that may otherwise have to be transferred out of the facility to a higher level of care.

Long-term effects: Possible revenue increase from being able to admit or retain more residents than possible in the past. Possible increased costs negatively impacting facilities that receive monetary penalties.

Anticipated effects on the public:
Adverse effects: No anticipated adverse effects on the public is anticipated.
Beneficial effects: Benefits to the public include adding training requirements to perform certain tasks, requiring manufacturer's instructions be followed, and utilizing nationally recognized infection control guidelines when carrying out such tasks, to help ensure these activities are carried out in a safe and effective manner.
Immediate effects: Ability for certain members of the public, such as diabetics, to have a wider range of choices as to where they receive care. Greater transparency to the public who will be able to see a facility's Centers for Medicare and Medicaid services star rating, if applicable, at the entrance of facilities.
Long-term effects: The long-term effects would be a continuation of the immediate effects over time.

7. The estimated cost to the agency for enforcement of the adopted regulation.

It is estimated it would cost $1,400 to conduct an initial inspection for each employment agency to provide non-medical services in the home and cost $700 a year to continue to license and regulate each agency. As the Division does not know how many agencies would be licensed in accordance to this new rule, a total cost cannot be estimated at this time. Enforcement related to all other areas in the proposed regulations would be incorporated into current licensing and regulatory activities; therefore, it is not anticipated that these activities would result in additional costs to the Division.

8. A description of any regulations of other state or government agencies which the adopted regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the regulation overlaps or duplicates a federal regulation, name the regulating federal agency.

The adopted regulations do not overlap or duplicate other state or federal regulations. The adopted regulations do clarify when a CLIA certificate is required from CMS in accordance with federal law.

9. If the regulation includes provisions which are more stringent than a federal regulation which regulates the same activity, a summary of such provisions.

The adopted regulations do not include provisions which are more stringent than federal regulations.

10. If the regulation establishes a new fee or increases an existing fee, a statement indicating the total annual amount the agency expects to collect and the way the money will be used.

The proposed regulations provide for a new licensing fee to license employment agencies as directed in SB 388 of the 2017 legislative session. The proposed new fee is $1,400 to conduct an initial inspection for each employment agency to provide non-medical services in the home and cost $700 a year to continue to license and regulate each agency. As the Division does not know how many agencies would be licensed in accordance to this new rule, we do not know the annual amount that would be collected. The fee would be used to license, inspect and otherwise regulate this new agency type.

The proposed regulations increase the monetary penalties, if imposed, that can be applied to health facilities as follows:

- For initial deficiencies with a severity level of four if the violation creates harm or a risk of harm to one person, an initial monetary penalty of $2,500 per deficiency must be imposed and if the violation creates harm or a risk of harm to more than one person an initial monetary penalty of $5,000 per deficiency must be imposed. This was increased from a monetary penalty of up to $1,000 per violation for a severity four violation.
- For initial deficiencies rated with a severity level of three and a scope level of three if the violation creates harm or a risk of harm to one person, a monetary penalty of $2,000 per deficiency must be imposed and if the violation creates harm or a risk of harm to more than one person an initial monetary penalty of $4,000 per deficiency must be imposed. This was increased from a monetary penalty of up to $800 per violation for a severity level of three and a scope level of three violation.
- For initial deficiencies with a severity level of three and a scope level of two or less if the violation creates harm or a risk of harm to one person, an initial monetary penalty of $1,500 per deficiency must be imposed and if the violation creates harm or a risk of harm to more than one person an initial monetary penalty of $3,000 per deficiency must be imposed. This was increased from a monetary penalty of up to $400 per violation for a severity level of three and a scope level of two or less violation.
- For initial deficiencies with a severity level of two and a scope level of three, an initial monetary penalty of $1,000 per deficiency may be imposed. This was increased from a monetary penalty of up to $200 per violation for a severity level of two and a scope level of three violation. The payment of this monetary penalty must be suspended if the facility has corrected the deficiencies within the time specified in the plan of correction approved by the Bureau.

It is unknown what the annual amount would be as the number of citations and number of patients/residents/clients impacted vary yearly. To give a rough estimate based on 2017 numbers if all citations of a three or four only impacted one resident it was initially estimated to be $130,000 in a year and if all the citations impacted more than one resident it was initially estimated to be $202,500 per year, and if it was a mix of the number of persons impacted, sometimes one person and sometime more than one, it would fall in between. This is based on all facilities paying the full sanction amount but more likely the amounts would be lower because any facility that

corrected the deficiencies, paid the penalty within 15 days and waived their right to a hearing would get a 25% reduction in their penalty.

In response to industry feedback the Division reduced the financial impact the proposed regulations would have on small businesses, as noted in number 4, which would further reduce the amounts estimated to be collected to approximately $65,000 in a year for citations that impact one resident and $130,000 per year for those that impact more than one resident. This may be further reduced if facilities use monetary penalties to correct first violations in lieu of paying a monetary penalty.

Also, there was concern expressed that a facility does not currently have the right to appeal. All facilities given a monetary sanction are issued a sanction notice which provides notice of the facility's right to appeal through a hearing process. The Division will set up a prehearing, an informal meeting to go over the issues, which may result in a resolution without going to hearing. This should alleviate the concern expressed that a facility would have to go directly to a hearing prior to having the facility's concerns being heard through an informal process. If the facility is not in agreement with the results of the pre-hearing meeting, the facility may proceed to the hearing process.

The money collected by the Division as administrative sanctions will be applied to the protection of the health, safety, well-being and property of recipients, including residents of facilities that the Division finds deficient.