DIVISION OF PUBLIC & BEHAVIORAL HEALTH
BUREAU OF HEALTH CARE QUALITY AND COMPLIANCE
LCB File No. R149-15

Informational Statement per NRS 233B.066

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

The need for the adopted regulation is to protect public safety, bring the regulations into compliance with Nevada Revised Statutes (NRS) 652.130, NRS 652.186 and NRS 652.123 and to reduce the burden on individuals and businesses by:

- Not requiring the laboratory director in which only an HIV waived test is performed to be a licensed physician. It also does not require personnel performing the test to obtain certification as an assistant if the person submits proof of successful completion of training approved by the Division.
- Expanding the types of healthcare professionals that can serve as an exempt laboratory director.
- Deeming a laboratory licensed pursuant to Nevada Revised Statutes (NRS) and Nevada Administrative Code (NAC) of Chapter 652 which is also permitted, as defined in NRS 450B.100, and certified laboratory personnel who work in the laboratory, to have met the payment of required certification and licensure fees, as applicable.
- Clarifying that a permit to operate a laboratory at a temporary location expires 90 days after the effective date of the permit.
- Clarifying that exempt laboratories must adopt nationally recognized laboratory safety guidelines.
- Expanding the certification that an applicant that holds a doctorate degree can use to qualify to be a licensed or registered laboratory director.
- Outlining the fee to be assessed for a laboratory that only performs waived HIV tests.
- Allowing a laboratory to add as many tests as it wants to on one application for a flat rate of $300, instead of requiring a $300 application fee plus $50 for each additional specialty or subspecialties in which tests will be performed.
- Bringing proficiency testing standards in line with federal regulation requirements.
- Providing a method for a technologist to obtain the required one year of experience in Nevada instead of having to go out of state to obtain the experience, if they don't already have the experience.
- Changing the time a provisional certificate is good for from 180 days after the date of issue with the ability to request no more than three provisional certificates to one provisional certificate that cannot be renewed which would be good for 18 months.

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;

Pursuant to NRS 233B.0608 (2) (a), the Division of Public and Behavioral Health has requested input from laboratories licensed in Nevada and licensed/certified laboratory personnel. Input was also received from the:

1) Adult Day Care Advisory Council;
2) Homes for Individual Residential Care Advisory Council;
3) Assisted Living Advisory Council; and the
4) Medical Laboratory Advisory Committee

The proposed regulations were sent to the Board of Nursing, Board of Pharmacy and Board of Medical Examiners.

A Small Business Impact Questionnaire was sent to medical laboratories and laboratory personnel along with a copy of the proposed regulation changes, in June of 2015. These were also posted on the Division's website and sent out through the Division's laboratory, medical and non-medical facilities listservs.

June 2, 2015 – The proposed regulations were presented to the Medical Laboratory Advisory Committee (MLAC). MLAC is composed of two pathologists, certified in clinical pathology by the American Board of Pathology, two medical technologists, a bioanalyst who is a laboratory director, a biochemist from the Nevada System of Higher Education and one licensed physician actively engaged in the practice of clinical medicine in this State. One of the roles of MLAC is to provide recommendations to the Board of Health relating to regulations. MLAC recommended restructuring the paragraphs related to who can serve as an exempt laboratory director. These were restructured so that each paragraph does not start off with, "In addition" and the word "or' was inserted to make it clear that any of the health care professionals listed in the paragraphs would be able to serve as the laboratory director.

December 17, 2015: A public workshop was held on the proposed regulations at the Division of Public and Behavioral Health located at 727 Fairview Drive, Suite E, Carson City and video conferenced to the Division's office located at 4220 South Maryland Parkway, Suite 810 in Las Vegas.

Two members of the public signed in at our Carson City office and both individuals signed in as supporting the proposed regulations.

Twenty-six individuals signed in at our Las Vegas location, twelve signed in as opposed to the proposed regulations, eleven signed in support, one signed in as undecided and two did not list a position.

Support for the proposed regulations expressed during the public workshop included:
One individual expressed support for expanding the types of healthcare professionals who can serve as an exempt laboratory director.

Concerns with the proposed regulations expressed during the public workshop included:
One individual expressed concern that she can give injections in HIRC (homes for individual residential care) homes but can't do glucose testing. She stated she can't accept certain residents because they need help with glucose testing and she feels this is discriminatory. She would like an exemption for group homes, HIRCs, and ADCs (adult day care) so they can do glucose testing with proper training through a certified medication program.

It was clarified that a HIRC, ADC, or group home who wants to apply to provide tests can do so as long as they meet current requirements by applying to HCQC for an exempt laboratory license.

Another individual expressed concerns regarding a nurse who doesn't have any advanced training such as a nurse practitioner, MD, or PhD to supervise a CLIA (Clinical Laboratory Improvement Amendments)-waived lab. He feels that to assume that any nurse can manage and train staff and have the necessary diagnostic skills strains credulity. He does, however, feel that a nurse practitioner has the necessary skills. He asked why Nevada has tougher regulations than the federal government on finger sticks. He made three recommendations to improve clinical care: One, let nurses work within their scope of care. Two, let caregivers do observations. Currently they are not allowed to check a weight, read a thermometer or do a blood pressure cuff reading. Three, allow caregivers with some training to do finger sticks with the patient's own machine. If they're using a community machine like those used in a medical lab, then require a nurse practitioner or MD to administer the test. He feels it's common sense for finger sticks to be permitted in group homes and HIRCs with proper training, since people do their own finger sticks at home.

It was clarified that the regulations currently under consideration only cover medical laboratories and do not affect NAC 449 regulations covering the administration of medications. The medical laboratory regulations deal strictly with testing only.

Concerns were expressed regarding the cost of applying for an exempt laboratory license and requiring a medical professional to be its director. She said the $1,000 a year fee is not realistic for a HIRC.

It was clarified that the fee is not $1,000 a year. The initial fee is $500 for two years and $300 to renew every two years. It was explained that it is understood that it may be cost prohibitive to have a physician for just one glucose monitor in a facility, and that's a reason for expanding the individuals who can serve as laboratory directors, including an R.N., if there's only one test involved.

It was also explained that HCQC does an initial inspection for tests being performed and if a new test is added, a separate application must be submitted, allowing HCQC to ensure that everyone is properly trained. If a test is added to a one-test lab, then it is no longer a one-test lab.

It was commented that there have been deaths associated with the use of waived tests. One individual questioned whether someone can die from a finger stick glucose test.

One individual asked if she was required to have a monitor like the one used in hospitals for testing residents at her facilities. She wondered if she could use the standard home unit since it is less costly.

It was clarified that the definition of an "advanced practice registered nurse" is basically what the State Board of Nursing defines as an APRN.

Written comments provided to the Division of Public and Behavioral Health included:
Support of the proposed changes because "these changes will improve access to care and remove unnecessary barriers currently impeding access to care in Nevada."

Support of the proposed regulations relating to the addition of the National Registry of Certified Chemists (NRCC) to the list of approved Board certifications that would be allowed to qualify as the laboratory director of a registered or licensed laboratory.

Opposition to the proposed changes because it was felt the proposed regulations would add more confusion and potentially lead to incomplete, less monitored care for disabled seniors who have diabetes and require assistance with finger sticks and insulin injections.

Recommended changes to the proposed regulations expressed during the public workshop process included:

One individual recommended that HCQC allow facilities to use standard home units, not have to pay a licensing fee, and that nurses be allowed to do what they're licensed to do, whether they're in a residential facility, hospital, or home health agency.

Allowing RN's who are owners are or who have a financial interest in a facility, to work within their scope of practice.

Allowing caregivers to perform and record basic observational tasks like weights, temps, and blood pressures and pulses.

Allowing medication techs to receive additional training on performing finger sticks and administer prefilled flex pens of varied medications including insulin.

Recommendation that APRN's be allowed to oversee a CLIA waived laboratory but not allow a nurse to be able to do so.

September 30, 2016 – A second public workshop was held on the proposed regulations at the Division of Public and Behavioral Health located at 727 Fairview Drive, Suite E, Carson City and video conferenced to the Division's office located at 4220 South Maryland Parkway, Suite 810 in Las Vegas.

In the Carson City office, ten people signed in with five people signing in support of the proposed regulations, one signing in support with an addition, one signing as opposed and three individuals not indicating their position on the proposed regulations on the sign in sheet.

In the Las Vegas office, seventeen people signed in with one person signing in as opposed and the rest did not indicate their position on the proposed regulations on the sign in sheet.

Below is an overview of the testimony provided during the public workshop.
A recommendation was made that dentists be added to the list of those who can serve as the laboratory director of an exempt laboratory.

One individual testified in full support of APRN's acting as exempt laboratory directors and that it was within their scope of practice to do so.

One individual stated there was no prevention of a laboratory tree under the regulations and provided an example of what was meant by this. The example provided was an office with five nurses and each nurse served as the laboratory director of that office allowing each of them to do different tests in one office. Another concern expressed was related to quality issues and that

people without laboratory experience don't have a good picture on how to evaluate tests. Allowing a lab to do a single test, with a focus on HIV screening, the largest population for syphilis, simple extension to then do a rapid syphilis test. She believes it is a danger to public health and healthcare in general. A concern that such laboratories would create an inspection burden. Our state inspectors are overburdened for them to go out to do one laboratory to assure appropriate evaluation and validation on tests may not be possible so putting in regulation that these waived tests can be done without any type of validation or proper control or education who are receiving the results. The safest of the CLIA waived test called the fingerstick glucose which the CDC says the risk is less than zero, or forgets exactly how it is said, but the risk is so low that doing the test incorrectly provides no risk, so because the CDC and CMS share that view we agree with them. This is very different from any CLIA waived test to their recommendation are narrow and focused and consistent with current standard of not sharing the meter.

It was expressed that exempt laboratories needed to comply with safety and efficiency standards.

One individual expressed concerns about allowing any nurse to do CLIA waived tests. He stated that noting one test is not specific enough, but even if it was fingerstick only with shared meters it should not be allowed. Adding fingersticks is over reaching due to liability insurance issues. He stated single patient use meters were okay. He also went on to say that patients using their own meters in adult day cares would be a problem because the meters would come and go with the patients. He stated it was okay for residential facilities for groups to do fingersticks with an individual's meter. He stated nurses working within their scope of practice is okay. He also stated that the CDC's position is that there is zero risk for fingerstick glucose testing.

One individual stated that the CLIA waived model used in SNF's should not be used in residential facilities. She opposes the regulations in the residential care facility setting.

She mentioned that the assisted living/residential facilities for groups industry worked closely with the Legislative Committee for Seniors, Veterans and Adults with special needs as well as the Legislative Commission subcommittee and that there was a post-acute care study that was looking as these issues and that Dr. Robin Titus and Dr. Joe Hardy were a part of it. She mentioned that it was brought to their attention that individual who lived there, if at home, friends, neighbors and daughters could check their glucose, blood pressure and heart rate and report it to the doctor but in residential facilities for groups it should not be allowed because they are not a CLIA lab. Each individual facility has to have its CLIA lab. This is ridiculous. It makes no sense because you can do it at home but not in an environment with more people looking after you that have close contact with the physician on all of these things. Administration of flex pen and managing diabetes makes sense so the legislature is coming up with a recommendation for the State Board of Health to adopt regulations to allow the

administration of the different types of observation tests as well as flex pens and other monitoring devices and glucose tolerance tests. We disagree with shared devices. Want to keep it with just personal devices.

An overview of written testimony included:

- Adding that all settings must have clear allowable patient types that include both diagnosis label and most importantly functional needs assessment. For example, if they need 24 hour protective supervision, help with medication and PRN medications and caregiving. In addition, define what patient types require the safety of a sprinkler and which patient types do not.
- Adding a requirement of public disclosure of locations for any shared living, congregate care, or any other site which provides any amount of protective supervision, assistance with medications, caregiving, to people who are not completely independent.
- Removing language which would allow certain health care professionals to serve as the laboratory director of an exempt laboratory that only performs one waived test because it is beyond current clinical practice standards.

October 12, 2016 – A second meeting was held before the Medical Laboratory Advisory Council (MLAC) meeting. MLAC's recommendation to the Board of Health was to move the proposed regulations forward with the following changes:

1) MLAC recommended that instead of allowing the individuals listed in Section 6, Subsection 2 to serve as the laboratory director of an exempt laboratory that performs one waived test that they only be allowed to serve in this capacity if only waived glucose testing is being performed.
2) MLAC recommended that the timeframe from which the director has to submit the plan of correction be changed from 10 calendar days to 14 calendar days.
3) MLAC recommended that if a technologist does not have the necessary experience to obtain certification as a technologist that he or she be required to have a provisional certificate in order to work.

A summary of the Hearing for Amendment of Nevada Administrative Code, Chapter 652 can be obtained by contacting the Bureau of Health Care Quality and Compliance, 727 Fairview Drive, Suite E, Carson City, NV 89701. Phone: 775-684-1030.

3. A statement indicating the number of persons who attended each hearing, testified at each hearing, and submitted written statements regarding the proposed 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 proposed 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

Fifty-two people were noted on the sign in sheet as having attended the March 2017 Board of Health. Of note, some of those individuals may have been at the hearing for other items being heard at the same hearing.

Five people testified in support of the proposed regulations:

Russ Phifer	National Registry of Certified Chemists (NRCC)	610-322-0657
Marc Julliard	MD Labs	530-574-7959
Robert Harding	Northern Nevada HOPES	775-750-8305
Cameron Duncan	Nevada Advanced Practice Nurses Association	775-843-8428

An APRN testified in Las Vegas (did not get name)

Two people testified in opposition:

Jeanne Bishop-Parise	Nevada Assisted Living Association	775-232-3379
Shawn McGivney	Doctors (according to BOH sign in sheet)	702-556-1639

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.

A Small Business Impact Questionnaire was sent to medical laboratories and laboratory personnel along with a copy of the proposed regulation changes, in June of 2015. These were also posted on the Division's website and sent out through the Division's laboratory, medical and non-medical facilities listservs.

Summary of Response

Summary Of Comments Received (71* responses were received out of 12,865 plus*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?**
No = 61 Yes = 5 No response/ unknown = 5	No = 62 Yes = 5 No response/ unknown = 4	No = 61 Yes = 5 No response/ unknown = 5	No = 64 Yes = 3 No response/ unknown = 4
Comments: Renewal Fee Increase liability insurance and push RFFG big and small into a medical insurance premium and out of the non-medical premiums they enjoy now. Lead to more negative images of the industry with misleading promises from the community. They promise a diabetes screening program when in fact it is just a finger stick without giving insulin program. I can't help but believe a common person will not understand the subtle distinction as	**Comments:** I am a DNP and I own a family practice office. Allowing nurse practitioners to be laboratory directors will save me $500/year. I have to pay a physician to be my laboratory director. If NP's were able to be lab director our clinic would experience >12,000.00 cost savings. As a nonprofit saving fees is important. This potentially can lower costs associated with director fees.	Comments: While less on my business directly because we will not be using this program since I believe it is unsafe. As a medical doctor I see these risks as industry wide and hurting/agitating seniors, increasing ER visits unnecessarily, and leading to many civil suits. I believe that most big companies will not use this either and will recognize the risk to their liability	**Comments:** Will allow clinic to operate our CLIA waived lab with less cost. 1) Cost Savings 2) Time Savings 3) Better oversight from EMS office of all providers not just a small annual percent. In general there are no benefits from providing misleading information to seniors

something the community senior and family should have known. Does not affect us I will need to increase charges for the one test that we do – a nasal smear. Will have financial site impact. To get an estimated cost would have to go to corporate side. NAC 652.380 A physician to obtain a board cert not related to their primary specialty requires an enormous amount of time to study. Thousands of dollars for training courses and cost of the board exam. All these regulations will further push competent physicians out of medicine. I don't know yet until inspection. Unknown Makes my business have a ridiculous financial burden I may not need but for brief amounts of time, yet have to maintain annually.	Remove the restriction for medical doctor. Will be in line with the 2013 changes for full practice authority for APRN. Elimination of secondary oversight and financial charge to be a lab that is more than over State EMS permit to operate. No. It only misleads seniors and families and doctors into thinking these facilities have a full time, fully functioning nurse, when in fact they do not. This is very misleading for the community. Does not affect us It will just increase my overhead costs and increase the cost to my patient for test. We won't be able to afford to perform the waived test with newly imposed fees. We barely make a profit so the fees will create a negative profit margin.	insurance. I fear small providers and small more private big assisted living facilities trying to do good but who lack the medical and risk management knowledge to keep themselves and residents safe. N/A Increase cost of patient care. No added benefit that I can see. Increased financial responsibility. Financially because a current service will not be able to be provided which will cause a reduction in revenue. Also, patients who entrust their physicians at our office to monitor PTT/INR levels will lose the benefit of having their test performed and adjusted, if necessary, at the same time without a delay in care.	apparently with the goal of discharging residents with complicated medical problems to non-medical facilities that can't manage and treat them. The issue is not doing a fingerstick but not having the full time RN's to give insulin. I do have ideas on how the state and industry can safely offer a complete diabetes screening program and will continue to share them as I and RCHCAN have in the last year. The industry remains open to sitting down and working with the state and HCQC and other agencies to find safe, cost effective, care options for the state that are clear, transparent and safe for seniors. This is not it by itself. It hurts the patients causing a delay in care. It hurts the physicians – taking away the ability to

	I won't know until inspection. Do not see anything beneficial all fees appear to be increasing. Only adds to what my low income, rural residents have to pay.	I don't know as of yet Unknown. Restricts residents right to live where the want to! Financial burden, more intrusive, unnecessary way to limit my ability to make a living, care for those in need, punish my business because someone else screwed up! Anyone can learn to do a glucometer blood sugar check – I know that from home health nursing over the years. Lay people and children do it yet we who care for seniors need a lab license – too far state – too far! No-	provide immediate care and hurts by removing a service that our patients want to be performed in their physician's office. I don't know until further inspection. **N/A** **Other Comments:** We perform only urine pregnancy tests on surgery patients. No other testing! Do not anticipate any adverse or beneficial effects. Our lab is an exempt lab, and there are no changes to fees that I can see.

Number of Respondents out of 12,865 plus	**Adverse economic effect?**	**Beneficial effect?**	**Indirect adverse effects?**	**Indirect beneficial effects?**
No	61	62	61	64
Yes	5	5	5	3
No Response/unknown	5	4	5	4

*questionnaires returned which indicated 150 or more employees were not included.
*questionnaires were also sent to the Board of Nursing, Board of Pharmacy and Board of Medical Examiners for distribution to their members.

A copy of the summary can be obtained by contacting the Bureau of Health Care Quality and Compliance, 727 Fairview Drive, Suite E, Carson City, NV 89701. Phone: 775-684-1030.

5. If, after consideration of public comment, the regulation was adopted without changing any part of the proposed 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 proposed.

The proposed regulations were modified after the public workshop processes and MLAC meetings. The main changes include:

1) All of MLAC's recommendations presented during the October 12, 2016 MLAC meeting, as outlined in number two, were incorporated into the proposed regulations.
2) Removing the requirement that if the Division cannot determine the qualifications of a license as a director that the Division is to submit the application to the Committee for its recommendation.
3) Adding CLIA approved Boards to the certification that an applicant that holds a doctorate degree can use to qualify to be a licensed or registered laboratory director.
4) Changing the provisional certificate time frame from a provisional certificate that expires 180 days after the date of issue with the ability to request no more than three provisional certificates to a provisional certificate valid for 18 months from the time of issuance without the ability to renew it. In addition, if a technologist does not have the necessary experience to obtain certification as a technologist, he or she shall be required to have a provisional certificate in order to work.
5) Allowing the individuals listed in Section 6, Subsection 2 to serve as the laboratory director of an exempt laboratory that only performs glucose waived test instead of any waived test.
6) Changing the timeframe from which the director has to submit the plan of correction from 10 calendar days to 14 calendar days.
7) The Board of Health adopted the regulations with one change, omitting the American Osteopathic Board of Internal Medicine from subsection (1) (b) of Section 16 to be replaced with the following language in Section 16, subsection 1: 1) Be a physician or osteopathic physician certified in the subspecialty of pulmonary disease by the American Board of Internal Medicine or any other nationally recognized board of internal medicine.

Medical laboratory regulations are specific to laboratory testing and do not cover medication administration, taking of blood pressures and other related items; therefore, none of these

recommended changes were made. The Board of Dental Examiners was called to obtain permission to add dentists to the list of health care professionals that can serve as an exempt laboratory director but permission was never received to add them.

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.

Adverse effects: No adverse financial effects are anticipated. There was concern expressed that there would be an increase in liability insurance and it would push residential type facilities into a medical insurance premium and out of non-medical premiums. The proposed regulations do not require businesses to offer laboratory services if they do not want to. Currently these businesses are able to provide laboratory services if licensing requirements are met, so the proposed regulations do not add an additional service that can be provided by these businesses.

Beneficial effects: It is anticipated that there would be a beneficial financial effect for some individuals and businesses. For example, one small business estimated a cost savings of $500 per year while others noted there would be no changes. Beneficial effects include offering these small businesses flexibility in determining what is best for their business and does not dictate that they must use a health care provider other than a physician to serve as an exempt laboratory director. In addition, many States do not require a physician or even a healthcare professional to serve as an exempt laboratory director. Each business would be able to make the determination based on their liability insurance what is best for them.

Immediate effects: As soon as the regulations become effective individuals would be able to immediately implement the changes in the proposed regulations, such as applying for an exempt laboratory without the requirement that a physician serve as the laboratory director or having an existing exempt laboratory make a change in director. This may result in immediate cost savings to these businesses.

Long term effects: It is anticipated the cost savings for certain businesses would have a long term effect as they would be accumulative through the years. For example, the small business that estimated a cost savings of $500 per year.

7. The estimated cost to the agency for enforcement of the proposed regulation.
At this time, it is estimated that there would be no additional cost to the agency to enforce the proposed regulations. It is anticipated that any increased workload caused by industry opening a medical laboratory to perform only waived HIV testing would be absorbed into exiting workload

by existing staff. In addition, a licensing fee of $150 for HIV testing laboratories would help offset any additional licensing costs. Emergency Medical Services staff would incorporate the inspection of a medical laboratory located in permitted emergency medical services and firefighting agencies into their current inspection workload. It is estimated that the other provisions in the proposed regulations would not result in an additional cost to the agency.

8. A description of any regulations of other state or government agencies which the proposed 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.

There are no other state regulations that overlap or duplicate the proposed regulations.

Although federal regulations (Centers for Medicare and Medicaid Services) cover some aspects addressed in the proposed regulations, federal regulations do not address issues specific to state licensure such as what is required for an application to obtain a state license. In addition, not all laboratories are federally certified by the Centers for Medicare and Medicaid Services therefore the federal regulations would not apply to state licensed only laboratories. This creates the need to also include the provisions in state regulations.

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

The Centers for Medicare and Medicaid Services (CMS) federal CLIA regulations do not have any requirements for the individual that serves as the laboratory director for an exempt laboratory. Nevada's current regulations require that the laboratory director of an exempt laboratory be a licensed physician as defined in NAC 652. The proposed regulations expand who can serve as an exempt laboratory director to include certain, other healthcare professionals licensed or certified in Nevada. This requirement does remain more stringent than federal regulations that do not require a healthcare professional to serve in this capacity but due to input received during the regulation development process it was felt that having a healthcare professional serve in this capacity be a requirement to help ensure the safety and well-being of Nevada's public.

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 manner in which the money will be used.

An initial licensing fee of $150 good for two years followed by a biennial renewal fee of $150 for the new laboratory type, HIV testing laboratory, is noted in the regulations. We anticipate having a total of seven HIV testing laboratories to start; although, we may have more in the future. We expect to collect $1,050 every two years from these 7 laboratories which comes out to $525 annually. We plan to use these funds to help offset the costs to license, inspect and regulate this new type of laboratory.