Support SB20-040 Licensure of Genetic Counselors

Sponsors: Senators Ginal & Todd and Representatives Buckner & Michaelson Jenet

Access to licensed genetic counselors prevents harm to consumers by ensuring that patients, other healthcare providers, and healthcare systems can identify and readily incorporate qualified genetic counselors into patient care -- before harm occurs. Since 2010, four case series detailing 90 examples of patient harm that occurred due to failure to properly involve a genetic counselor in patient care have been published. The 2019 installment (Farmer et al., The Cancer Journal, 25(4):231-236, 2019) details 25 cases where eventual inclusion of a genetic counselor prevented ongoing harm to a patient, often after another provider had conducted erroneous or unnecessary genetic tests, misinterpreted genetic testing results, failed to provide adequate informed consent for genetic testing, or otherwise erred. Lack of access to genetic counselors in these cases would have had serious ramifications, ranging from failure to identify the presence of a hereditary cancer predisposition syndrome, provision of erroneous reproductive risk information, and delayed diagnosis of a genetic condition resulting in medical mismanagement, to thousands of dollars wasted on incorrect or unnecessary genetic testing.

Licensure creates an environment where genetic counselors become fully integrated into the healthcare delivery system. Costs are reduced because genetic counselors have the expertise to select the right test for the right individual through the right laboratory for the right price. This saves money for the healthcare system (whatever payer is involved), as well as for the individual patient who is responsible for co-payments and other out-of-pocket costs. For example, a provider might incorrectly order an extensive genetic test that could cost thousands of dollars when a much less and more limited genetic test might provide the same information yet cost only several hundred dollars. As Dr. Mark Lovell (Pathologist and Laboratory Medical Director, Children's Hospital Colorado) said as part of his testimony to the Senate in 2019: "Genetic counselors are uniquely qualified to help fill this gap by assisting the medical community in applying this powerful new knowledge for the benefit of patients and their families. At Children's I work with a genetic counselor who helps save Colorado Medicaid over $125,000 annually in unnecessary testing that had been ordered by well-meaning but uninformed physicians."

Evidence-based research demonstrates that genetic counselors provide a net savings when they are utilized in the genetic testing process. Examples include the following:

- Priority Health, a private insurance company in Michigan, mandated the use of genetic counselors prior to the approval of certain genetic tests. This program prevented over $10 million worth of inappropriate tests and a net savings of $7.2 million.
- The Department of Veterans Affairs Genomic Medicine Service recently conducted a cursory chart review of their first 100 genetic referrals, in which testing was ordered for 19 patients by a practitioner other than a licensed genetic counselor. These tests would have cost taxpayers $109,369 and after review by a genetic counselor, only $18,345 of genetic tests were determined to be medically indicated for a cost savings of $91,024.
- Licensed genetic counselors at ARUP Laboratories performed a clinical review of all genetic tests over an 11 month period. They cancelled or changed inappropriately ordered genetic tests for an average cost savings of $36,500 per month, representing approximately 30 percent of all complex genetic tests ordered.

Licensure codifies that someone practicing as a genetic counselor is required to be certified. This protects consumers by ensuring that they and healthcare practitioners can confidently identify qualified genetic counselors. Without a licensure requirement, anyone can open a clinic and call themselves a genetic counselor and the state has no recourse. Recently, there have been pop up laboratories around the country that claim to provide genetic counseling and hire people without any degree or training in genetics. This poses a threat to consumers of genetic services in Colorado that SB 19-133 addressed. It's important to remember that people make critical and irreversible decisions based on genetic information, such as women undergoing preventive

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surgery to remove their breasts or ovaries in order to reduce their risk of cancer. If a genetic counselor is negligent, women may undergo this type of surgery unnecessarily, leading to everlasting physical, emotional, and psychological damage, as well as wasted financial resources.

Given that the majority of states have passed licensure bills and many others have them in progress – including all the surrounding states, the lack of licensure in Colorado makes the state attractive for genetic counselors who have lost licenses in other states or are not able to get a license in the first place. These places the public in the state of Colorado at-risk of being subject to sub-par genetic counseling services.

The genetic counselor profession is not new, as the first class graduated in 1971. It is one of the fastest growing healthcare professions in the country. It is also one of the preeminent STEM professions for women as they make up 95% of the profession. There are currently over 5,000 genetic counselors in the United States and the profession has doubled in size over the previous ten years. Over that same time licensure of genetic counselors increased from just a couple states to twenty-nine states. The profession is expected to double again in the next ten years.

Supporters:

Colorado Medical Society
Colorado Radiological Society
Denver Health
Children's Hospital Colorado
University of Colorado Cancer Center
Rocky Mountain Cancer Centers
Colorado Chapter of the American Academy of Pediatrics
Colorado Ovarian Cancer Alliance
Chronic Care Collaborative

For More Information Please Contact: Katie Wolf (720)365-3990 or katie@wolfpublicaffairs.com

Genetic Screening Technician - Entry Level

Bright Clinical - Denver, CO

$48,000 - $60,000 a year - Part-time, Contract, Commission

Apply Now

Job Type:

Part-time (possibility of full-time employment 90 days after hire)

Location:

The greater Denver, CO area

Education:

High shool diploma (required)

Experience:

- This is an entry-level position, but the ideal candidate will have some experience interacting with and serving the general public.
- Although this is not a traditional sales position, sales experience would be valuable.

Job Summary:

Genetic screening can help people to understand the likelihood of certain cancers so that preventative care and planning can be recommended. A separate genetic marker test can also determine the likely effectiveness of certain medications. These tests are now covered by some public assistance insurance providers at no cost to the patient. This means that these important preventative measures are no longer *only* available to people of means.

Genetic Screening Technicians arrange testing sessions at appropriate locations and guide patients through a brief interview and an oral swab test for genetic markers that determine propensity for cancer and medication suitability.

Screeners are paid per test/patient. There is no upper limit. A screener who administers an average of 10 tests per week (approximately 20 hours) can expect to be paid approximately $1,500/week.

Requirements:

- Must be at least 18 years old
- Professional and personable presentation
- Outgoing and comfortable speaking with prospective patients
- This role requires a self-starting person who takes initiative to get a job done well.
- This job fills an important community service for underserved populations. The person in the role should be interested in community improvement and service.

Please apply through the Indeed.com link at the bottom of this posting.

Job Types: Part-time, Contract, Commission

Salary: $48,000.00 to $60,000.00 /year

Experience:

- Sales: 1 year (Preferred)

Education:

- High school or equivalent (Preferred)

22 hours ago

Human Genome Landmarks

Selected Genes, Traits, and Disorders

www.ornl.gov/hgmis/posters/chromosome

genomics.energy.gov

246 million base pairs **1**

243 million base pairs **2**

199 million base pairs **3**

191 million base pairs **4**

181 million base pairs **5**

170 million base pairs **6**

158 million base pairs **7**

146 million base pairs **8**

136 million base pairs **9**

135 million base pairs **10**

134 million base pairs **11**

132 million base pairs **12**

113 million base pairs **13**

105 million base pairs **14**

100 million base pairs **15**

90 million base pairs **16**

81 million base pairs **17**

76 million base pairs **18**

63 million base pairs **19**

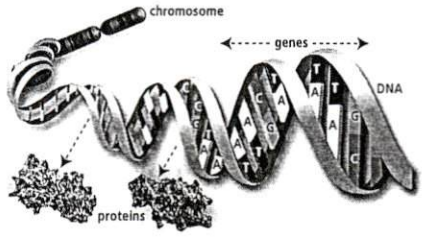
63 million base pairs **20**

46 million base pairs **21**

49 million base pairs **22**

153 million base pairs **X**

50 million base pairs **Y**



A Closer Look

Chromosomes are tightly coiled microscopic structures made up mainly of DNA, which consists of four different building blocks called bases (A, T, C, and G). The four bases are repeated millions of times to form each chromosome. The entire human genome consists of 23 pairs of chromosomes with one chromosome in every pair coming from each parent. With few exceptions (e.g., red blood cells), each of the trillions of cells in the human body contains a complete set of chromosomes—the genome.

The color-banded figures in this poster are simplified representations (ideograms) of chromosomes, which can be distinguished by observing their features through a light microscope. Such features include length, position of a constricted region (centromere), and the particular patterns of light and dark bands that result from treatment with stains.

Genes are chromosome pieces whose base sequence (e.g., ATTCGGA) determines how, when, and where the body makes each of the many thousands of different proteins required for life. Humans have an estimated 35,000 genes, with an average length of about 3000 bases. Genes make up less than 2% of human DNA; the remaining DNA has important but still unknown functions that may include regulating genes and maintaining the chromosome structure.

Researchers hunt for disease-associated genes by looking for base changes found only in the DNA of affected individuals. Numerous disorders and traits mapped to particular chromosomes are displayed on this poster. Some disorders, such as cystic fibrosis (chr. 7) and sickle cell anemia (chr. 11), are caused by base sequence changes in a single gene. Many common diseases such as diabetes, hypertension, deafness, and cancers have more complex causes that may be a combination of sequence variations in several genes on different chromosomes, in addition to environmental factors.

In April 2003, scientists in the International Human Genome Project (HGP) completed a highly accurate, 3-billion base pair human genome reference DNA sequence. The completion of the HGP coincided with the 50th anniversary of the publication of the structure of the DNA molecule by James Watson and Francis Crick. This achievement earned them the Nobel Prize and spawned the new field of molecular biology that led to the inception of the HGP in 1990. DNA sequences are being obtained for the genomes of many other organisms as well and are critical for comparative studies leading to a greater understanding of human biology and that of all living organisms.

A New Era of Customized Medicine. Knowing the DNA sequence is important because it affects responses to particular medicines, resistance to infections and toxins, and it may even influence behavior. Sequence variations also can cause or contribute to such disorders as those named on this poster.

These new data and powerful DNA analysis tools will usher in a new era of medicine that could allow doctors to detect disease at earlier stages, make more accurate diagnoses, and customize drugs and other medical treatments to fit an individual's own DNA sequence. The eventual understanding of gene functions will lead to more focused and effective treatments with fewer side effects.

For More Information

- Human Genome Project Information: Comprehensive HGP information and a look at the "new biology" of the 21st century
  www.ornl.gov/hgmis/home.shtml
- Genomics and Its Impact on Science and Society: A Primer
  www.ornl.gov/hgmis/publicat/primer/
- Genome Education Resources
  www.ornl.gov/hgmis/education/education.shtml
- DOE Genomics:GTL: Explores how microbial and plant genomes function for bioenergy and other applications
  http://genomicsgtl.energy.gov
- Medicine and the New Genetics: How genetic technologies will revolutionize medicine
  www.ornl.gov/hgmis/medicine/medicine.shtml
- Nature Human Genome Collection: Detailed analyses of all the chromosomes
  www.nature.com/nature/supplements/collections/humangenome
- National Human Genome Research Institute: National Institutes of Health genome program
  www.nhgri.nih.gov
- Careers in Genetics and the Biosciences: Resources for students and teachers
  www.ornl.gov/hgmis/education/careers.shtml
- DOE Joint Genome Institute: Facility for integrated high-throughput sequencing and computational analysis
  http://jgi.doe.gov
- Ethical, Legal, and Social Issues: Implications surrounding use of genome data
  www.ornl.gov/hgmis/elsi/elsi.shtml

Poster Sponsor
U.S. Department of Energy
Office of Science
www.sc.doe.gov

Poster Contacts
Prepared by Jody Wyrick and Denise Casey
Genome Management Information System
Oak Ridge National Laboratory
1060 Commerce Park, MS 6480
Oak Ridge, TN 37830

Free print copy: 865.574.0597 or
www.ornl.gov/hgmis/posters/chromosome

Explore the Human Genome Online! Gene Gateway

www.ornl.gov/hgmis/posters/chromosome

Step-by-step instructions for using the Web to learn about:

Genetic Disorders
- Causes, inheritance, symptoms, diagnosis, treatments
- Associated genes
- Support groups and organizations
- Genetic health professionals
- Articles and other materials

Genes and Proteins
- Gene name, symbol, size, protein product
- Chromosome maps
- Gene and protein sequence data
- Similar sequences in other organisms
- Gene mutations associated with disorders
- Molecular structures of proteins

Legend

Regions reflecting the unique patterns of light and dark bands seen on human chromosomes stained to allow viewing through a light microscope.

The centromere, or constricted portion, of each chromosome.

Chromosomal regions that vary in staining intensity and sometimes are called heterochromatin (meaning "different color").

Variable regions, called stalks, that connect a very small chromosome arm (a "satellite") to the chromosome.

Information Sources

Genes associated with the disorders and other traits listed on this poster were selected from *Online Mendelian Inheritance in Man* (OMIM), which designated the status of each of these as confirmed or provisional as of July 2005. Listing of genes on Y chromosome updated November 2002. The number of base pairs reported for each chromosome is based on finished human genome sequence data from the National Center for Biotechnology Information Build 34, Version 2, accessed February 4, 2004 (www.ncbi.nlm.nih.gov/genome/guide/human/).

U.S. DEPARTMENT OF
ENERGY
Office of Science
Biological and Environmental Research Program

Genomic Science Program
genomics.energy.gov

Fiscal Year 2020-21 Information Technology Request

Public Health and Environment

Newborn Screening Information Management System

PRIORITY NUMBERS 2021026

Prioritized By	Priority	
DeptInst	1 of 1	
OSPB	NP of 16	Recommended for funding.

PRIOR APPROPRIATION AND REQUEST INFORMATION

Fund Source	Prior Approp.	FY 2020-21	FY 2021-22	Future Requests	Total Cost
CF	$0	$1,575,000	$0	$0	$1,575,000
Total	$0	**$1,575,000**	$0	$0	$1,575,000

PROJECT STATUS

This is the first time the department has requested funding for this project.

PROJECT DESCRIPTION

The Colorado Department of Public Health and Environment (CDPHE) is requesting cash funds spending authority to replace and upgrade the laboratory information management system (LIMS) that supports the Colorado Newborn Screening Program (CONBSP).

According to the department, the CONBSP screens specimens from approximately 70,000 newborns a year around the state to detect a variety of medical conditions in order to connect infants with specialty care. Newborn screenings usually occur once at 24 to 48 hours of life and once between 8 and 14 days of life. CONBSP reported 135,000 specimens screened in 2018. This program also analyzes screen samples for newborns in Wyoming and from regions of Arizona. There are over 800 unique sample submitters and 4,000 pediatricians identified as care providers in the program.

CDPHE estimates that approximately 80 to 100 Colorado newborns are identified as being born with a screened disorder per year. The department states that each condition on the screening panel has treatment options as long as the condition is identified in a timely manner. New disorders are added to the screening panel by the Colorado Board of Health (Section 25-4-1004(1)(c), C.R.S.). The Colorado Board of Health must consider four specific criteria when adding a new disorder, including determining the costs and benefits. According to the Department, as the conditions considered for the screening panel increase in clinical complexity, the amount of screening data used to assess the newborn's risk also increases, which puts greater demand on the accuracy of the LIMS and the ability of the system to manage the data.

The LIMS supports the CONBSP in a variety of ways, including:

- analyzing screened samples;
- ensuring regulatory compliance;
- tracking operational logistics; and
- transmitting newborn data.

This project will move the LIMS from a legacy Microsoft system to a cloud browser-based system.

ROJECT JUSTIFICATION

According to CDPHE, this project will benefit the program for the following reasons:

Replace obsolete technology. CDPHE explains that Microsoft will no longer support the version of software that

the LIMS operates on starting in January 2020. As a result, this project will mitigate future security risks associated with using an unsupported technology which will not get security patches and support from the vendor in the future. The department also states that the current system cannot be supported internally, so once the vendor no longer supports it, CONBSP will not be able to add new conditions to the screening panel.

Systems Integration Opportunities. The department states that the current LIMS is a closed system, which requires a user to have the software physically installed on the operator's computer in order to be accessed. With this project moving the system to a cloud browser-based solution, the department hopes to connect the LIMS to other department internal data systems such as the electronic health record (EHR) systems used by major birthing facilities in order to improve data sharing capabilities.

Resolve Technical Issues. According to the department, the current LIMS experiences multiple errors across many applications causing CONBSP staff time to be used investigating those issues. The department hopes to resolve many of the issues currently experienced with this project including decreasing the time to create queries within the system and demographic data discrepancies.

The department also states that if this project is not funded and the LIMS fails in the future, the state would have to send screened samples to labs in other states, which would increase costs of the program and cause delays for results.

PROJECT COST INFORMATION

The department estimated the cost of this project based on responses to the request for information (RFI) process the department completed in spring 2019.

Cash funds. The source of cash funds is the Newborn Screening Cash Fund (Section 25-4-1006, C.R.S). The revenues in this fund are generated from fees assessed on newborn screening samples. These funds have been used in the past to support the administration, staffing, and equipment used in the CONBSP and to support the LIMS.

PROJECT COST INFORMATION, CONT.

Item	Estimated Cost
System Installation and Training	$900,000
Network Upgrades	$110,000
Project Manager	$140,000
Other Hardware	$200,000
IV&V	$150,000
5 percent Contingency	$75,000
Total	**$1,575,000**

PROJECT RESEARCH

The department states that it began researching new systems in 2017 as a result of the number of technical issues experienced in the LIMS. The current LIMS was purchased over 10 years ago and the number of technical issues has increased over time. The department also states that it discussed information management and data sharing capabilities with other states who use similar systems, such as Utah.

CDPHE says that the new LIMS may also be hosted on the Governor's Office of Information Technology (OIT) servers once a vendor is selected if it is determined to be more beneficial than a cloud-based solution.

Fiscal Year 2020-21 Information Technology Request

Public Health and Environment

Newborn Screening Information Management System

PROJECT SCHEDULE

	Start Date	Completion Date
Planning	July 2020	June 2021
Implementation	July 2021	October 2021
Testing	October 2021	December 2021
Closing	January 2022	

on documentation verified by the department, that the unregulated professional or occupational group poses an **imminent threat** to public health, safety, or welfare, **the department** shall promptly notify the proponents of the proposed regulation and the legislative council of the general assembly of the imminent threat and shall submit to the legislative council the documentation on which it **bases its finding of imminent threat**. Within thirty days after receipt of the notice and documentation from the department, the legislative council shall conduct a hearing to examine the documentation and determine whether it concurs with the department's finding that an imminent threat exists. In conducting its examination, the legislative council shall consider whether regulation of the professional or occupational group without first obtaining an analysis and evaluation pursuant to paragraph (a) of this subsection (3) will substantially alter the impact on public health, safety, or welfare. The department may forego the analysis and evaluation only if the legislative council notifies the department that the legislative council concurs with the department's finding of imminent threat to public health, safety, and welfare.

(4) (a) (Deleted by amendment, L. 96, p. 796, § 7, effective May 23, 1996.)

(b) In such hearings, the determination as to **whether** such **regulation** of an occupation or a profession is **needed** shall be based upon the following **considerations**:

(I) Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public, and whether the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;

(II) Whether the public needs, and can reasonably be expected to benefit from, an assurance of initial and continuing professional or occupational competence;

(III) Whether the public can be adequately protected by other means in a more cost-effective manner; and

(IV) Whether the imposition of any disqualifications on applicants for licensure, certification, relicensure, or recertification based on criminal history serves public safety or commercial or consumer protection interests.

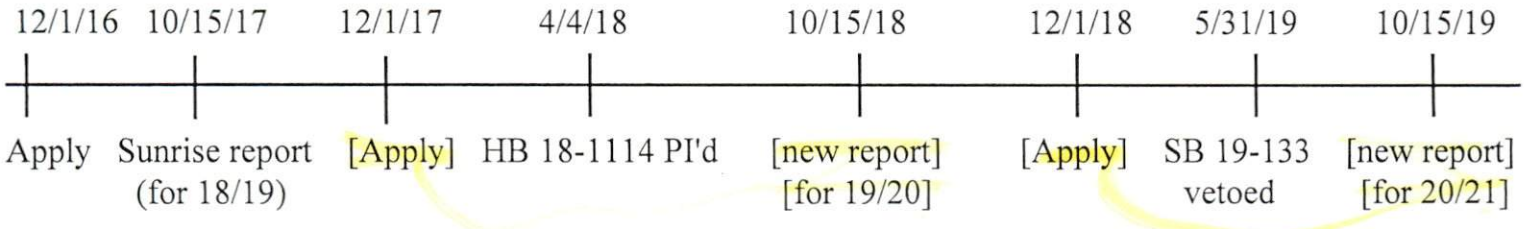
(c) (Deleted by amendment, L. 96, p. 796, § 7, effective May 23, 1996.)

(5) Repealed.

(6) (a) Except as provided in paragraph (b) of this subsection (6), the **supporters** of regulation of a professional or occupational group **may request members** of the general assembly to present appropriate **legislation** to the general assembly **during each of the two regular sessions** that immediately succeed the date of the report required pursuant to subsection (3) of this section without the supporters having to comply again with the provisions of subsections (2), (3), and (4) of this section. Bills introduced pursuant to this subsection (6) shall count against the number of bills to which members of the general assembly are limited by any joint rule of the senate and the house of representatives.

(b) If, pursuant to paragraph (b) or (c) of subsection (3) of this section, the department of regulatory agencies declines to conduct an analysis and evaluation of the proposed regulation of a professional or occupational group and **reissues a prior report** on the proposed regulation of the same professional or occupational group **or** finds that the unregulated professional or occupational group poses an **imminent threat** to public health, safety, or welfare, as confirmed by the legislative council of the general assembly, the **supporters** of the regulation of the professional or occupational group **may request** that members of the general assembly present appropriate **legislation** to the general assembly during each of **the next two regular sessions** that begin after the date the department reissues its original report on the proposed regulation or the date on which the legislative council notifies the department that it concurs in a finding of imminent threat pursuant to paragraph (c) of subsection (3) of this section, whichever is applicable.

(7) This section is exempt from the provisions of section 24-1-136 (11), and the periodic reporting requirement of this section shall remain in effect until changed by the general assembly acting by bill.



24-34-104.1. General assembly sunrise review of new regulation of occupations and professions. (1) The general assembly finds that regulation should be imposed on an occupation or profession only when necessary for the protection of the public interest. The general assembly further finds that establishing a system for reviewing the necessity of regulating an occupation or profession prior to enacting laws for such regulation will better enable it to evaluate the need for the regulation and to determine the least restrictive regulatory alternative consistent with the public interest.

(2) (a) For proposals submitted on or after July 1, 2012, any professional or occupational group or organization, any individual, or any other interested party that proposes the regulation of any unregulated professional or occupational group shall **submit** the following **information** to the department of regulatory agencies no later than **December 1** of any year for analysis and evaluation during the following year:

(I) A description of the group proposed for regulation, including a list of associations, organizations, and other groups representing the practitioners in this state, and an estimate of the number of practitioners in each group;

(II) A definition of the problem or problems to be solved by regulation and the reasons why regulation is necessary;

(III) A statement of support for the proposed regulation as described in paragraph (b) of this subsection (2);

(IV) The reasons why certification, registration, licensure, or other type of regulation is being proposed and why that regulatory alternative was chosen;

(V) The benefit to the public that would result from the proposed regulation;

(VI) The cost of the proposed regulation; and

(VII) A description of any anticipated disqualifications on an applicant for licensure, certification, relicensure, or recertification based on criminal history and how the disqualifications serve public safety or commercial or consumer protection interests.

(b) The department shall review a proposal to regulate a professional or occupational group only when the party requesting the review files a statement of support for the proposed regulation that has been signed by at least ten members of the professional or occupational group for which regulation is being sought or at least ten individuals who are not members of the professional or occupational group.

(3) (a) Except as provided in paragraph (b) or (c) of this subsection (3), the department of regulatory agencies shall **conduct an analysis** and evaluation of any proposed regulation submitted on or after July 1, 2012. The analysis and evaluation must be based upon the criteria listed in paragraph (b) of subsection (4) of this section. The department of regulatory agencies shall **submit a report** to the proponents of the regulation and to the general assembly no later than **October 15** of the year following the year in which the proposed regulation was submitted.

(b) (I) After review of a proposal to regulate a professional or occupational group that was submitted on or after July 1, 2012, the department of regulatory agencies **may decline** to conduct an analysis and evaluation of the proposed regulation only **if** it:

(A) Previously conducted an analysis and evaluation of the proposed regulation of the same professional or occupational group;

(B) **Issued a report not more than thirty-six months prior** to the submission of the current proposal to regulate the same professional or occupational group; **and**

(C) Finds that **no new information** has been submitted that would cause the department to alter or modify the recommendations made in its earlier report on the proposed regulation of the professional or occupational group.

(II) If the department of regulatory agencies declines to conduct an analysis and evaluation pursuant to this paragraph (b), the department shall reissue its earlier report on the proposed regulation to the proponents of the regulation and the general assembly no later than October 15 of the year following the year in which the proposed regulation was submitted.

(c) If the department receives a proposal to regulate a professional or occupational group indicating, based