DIVISION OF PUBLIC & BEHAVIORAL HEALTH BUREAU OF HEALTH CARE OUALITY AND COMPLIANCE

Medical Facilities and Other Related Entities LCB File No. R133-18

<u>Informational Statement per NRS 233B.066</u>

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

As a condition to receiving certain grants, existing federal law requires a state to require the development of a plan of safe care for an infant born with and identified as being affected by substance abuse or withdrawal symptoms resulting from prenatal drug exposure or a fetal alcohol spectrum disorder. The purpose of sections 2 to 8 of the adopted regulations is to ensure Nevada's CARA Plan of Care is in line with federal regulations, including the requirement that the Division monitor, in accordance with 42 U.S.C. § 5106a(b)(2)(B)(iii)(II), the implementation of each plan of safe care that it receives pursuant to section 7 of the adopted regulations to ensure that the infant to whom the plan pertains and his or her family or caregiver are receiving appropriate services.

42 U.S.C. § 5106a(b)(2)(B)(iii)(II),

"(b)Eligibility requirements

- (2) Contents A State plan submitted under paragraph (1) shall contain a description of the activities that the State will carry out using amounts received under the grant to achieve the objectives of this subchapter, including—
- (B)an assurance in the form of a certification by the Governor of the State that the State has in effect and is enforcing a State law, or has in effect and is operating a statewide program, relating to child abuse and neglect that includes—
- (iii) the development of a plan of safe care for the infant born and identified as being affected by substance abuse or withdrawal symptoms, or a Fetal Alcohol Spectrum Disorder to ensure the safety and well-being of such infant following release from the care of health care providers, including through—
- (II) the development and implementation by the State of monitoring systems regarding the implementation of such plans to determine whether and in what manner local entities are providing, in accordance with State requirements, referrals to and delivery of appropriate services for the infant and affected family or caregiver;"

The remaining sections of the adopted regulations requiring certain hospitals to be primarily engaged in providing the services described in 42 U.S.C. § 1395x(e)(1) to inpatients, to be deemed to meet Centers for Medicare and Medicaid Services (CMS) standards by an accrediting organization approved by CMS and revising the definitions of NAC 449.289 "inpatient" and NAC 449.297 "outpatient" are being moved forward due to industry feedback that some acute care hospital applicants in urban areas are opening independent smaller hospitals not associated with a larger hospital network that function more like an outpatient emergency services facility than a hospital. Concerns expressed included placing a burden on full service hospitals who would end up taking patient transfers from these smaller hospitals not capable of meeting the full

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needs of patients. In addition, a concern was expressed that these types of hospital may only accept private pay patients which could result in financial difficulties for some patients.

42 U.S.C. § 1395x(e)(1)

- "§ 1395x. Definitions For purposes of this subchapter—
- (e) Hospital The term "hospital" (except for purposes of sections 1395f(d), 1395f(f), and 1395n(b) of this title, subsection (a)(2) of this section, paragraph (7) of this subsection, and subsection (i) of this section) means an institution which— (1) is primarily engaged in providing, by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;"
- 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 - October 30, 2018:

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 via teleconference and it was also video conferenced to the Division's office located at 4220 South Maryland Parkway, Suite 810, in Las Vegas.

Six individuals signed the sign-in sheet in the Carson City location in support of the proposed regulations.

Five individuals signed the sign-in sheet in the Las Vegas location, with one person in support, one person in support/neutral of the adopted regulations, and the remaining individuals not indicating their position.

There were several individuals participating on the teleconference line at approximately 13 participants.

Oral testimony provided during the public workshop included support for the proposed regulations, noting sections 9 to 15 were important updates, support for the Nevada Hospital Association's position, support for full CMS certification and EMTALA (Emergency Medical Treatment and Labor Act) requirements.

Others requested clarifications on the proposed regulations and one individual requested the Division create educational handouts related to the CARA Plan of Care.

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One individual expressed concern that the proposed regulations conflicted with CMS regulations.

There were no recommendations made to change the proposed regulations during the public workshop and there were no small business impact questionnaires returned; therefore, there were no revisions made to the adopted regulations except the change of name to CARA Plan of Care.

Public Hearing - December 7, 2018:

A public hearing was held on December 7, 2018, via videoconference, at the following locations:

Division of Public and Behavioral Health
4150 Technology Way
Room #303
Carson City, NV 89706
AND
Grant Sawyer Office Building
555 E. Washington Ave.
Las Vegas, NV 89101

One individual testified that she was concerned about the CARA plan of care form and the length of it. She noted the need for further enhancements of the form.

One individual testified she believes hospitals need to be CMS certified and therefore bound by EMTALA. She noted emergency care should be for all regardless of ability to make payment. She noted legislation was being worked on. Written testimony was also provided and is included with this informational statement. Another individual testified in support of this position.

An attorney representing the Nevada Hospital Association testified in support of sections 9 to 15 of the proposed regulations.

The Board of Health adopted the proposed regulations with the errata that was presented.

The public workshop notice was posted on the LCB website on October 4, 2018 and distributed to licensed hospitals and pending hospital and obstetric center applicants on October 8, 2018.

The public hearing notice was posted on the LCB website and distributed to licensed hospitals, pending hospital and obstetric center applicants by October 31, 2018.

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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

- 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 requested input from licensed hospitals and pending hospital and obstetric center applicants (there are currently no licensed obstetric centers in Nevada) via the small business impact questionnaire. An electronic notice was sent to licensed hospitals, pending hospital and obstetric center applicants with information on how to provide

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feedback on the adopted regulations with a link to the small business impact questionnaire and to the adopted regulations on June 20, 2018. These were also posted on the 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?

Below is a summary of the responses to the questionnaire.

Summary of Comments Received (0 responses were received out of 72 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	Yes	Yes	Yes
No	No	No	No

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.

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There were no recommendations made to change the proposed regulations during the public workshop and there were no small business impact questionnaires returned; therefore, there were no revisions made to the proposed regulations except the change of name to CARA Plan of Care. The change of name was made to avoid confusion with a similarly named plan.

The Board of Health did not recommend any changes during the public hearing process and adopted the proposed regulations with the errata.

There was mention during the public hearing that any further changes to regulations (based on the testimony provided at the public hearing) could be addressed at a later time.

- 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: There may be a financial impact to businesses that are not exempt from obtaining accreditation by an approved national accrediting organization which will be required to obtain accreditation. Costs to become accredited may vary depending on the accrediting organization and other factors, such as average daily census. The Joint Commission, one popular accrediting organization, notes on its website fees include an on-site survey fee and annual fee, both based upon an organization's "average daily census" and services provided. It notes the average accreditation annual fee for an organization serving approximately 100 patients or residents each day is \$2300. It also notes that there are additional costs for any certifications. Beneficial effects: There are no anticipated financial beneficial effects to businesses.

Immediate effects: Newly opened businesses that are required to obtain accreditation in accordance with the adopted regulations would have an immediate adverse financial effect, as noted in the adverse effects section, upon initial application (no later than 12 months after obtaining an initial license).

Long-term effects: There would be continued renewal accreditation costs for those hospitals impacted by the regulatory change.

Anticipated effects on the public:

Adverse effects: There are no anticipated adverse effects to the public.

Beneficial effects: Beneficial effects to the public includes the development of CARA plans of care for infants born with a fetal alcohol spectrum disorder, affected by substance abuse or experiencing symptoms of withdrawal from a drug as a result of exposure to the drug in utero, to ensure the infant and the infant's family or caregiver receives any necessary services to ensure

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the safety and needs of the infant are met.

Immediate effects: Upon passage of the regulations, CARA plans of care will be required to be developed in accordance with the regulations and to be monitored by the Division to ensure that the infant to whom the plan pertains and his or her family or caregiver are receiving appropriate services.

Long-term effects: Infants and their family or caregivers will continue to receive services to meet the needs of the infant.

- 7. The estimated cost to the agency for enforcement of the adopted regulation. No costs are anticipated to the Division of Public and Behavioral Health for enforcement of the adopted regulations. The workload created by these adopted regulations, requiring the Division to monitor CARA plans of care, will be absorbed into the Division's existing workload; therefore, no additional costs to carry out the adopted regulations is anticipated at this time.
- 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.

There are no other state regulations addressing the same activity. Although there is a federal Comprehensive Addiction and Recovery Act (CARA), Public Law 114-198, the federal law requires that a State plan address the health and substance use disorders (SUD) treatment needs of the infant; therefore, the adopted regulations do not duplicate federal law but instead helps to carry it out.

Although Centers for Medicare and Medicaid Services (CMS) federal regulations do address inpatient services and CMS standards, CMS certification is a voluntary program; therefore, state regulations are required to cover any hospitals that may chose not to become CMS certified.

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 are not 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 manner in which the money will be used.

The adopted regulations do not establish a new few or increase an existing fee.