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November 9, 2018

MEMORANDUM

To:	Jon Pennell, DVM, Chair
	State Board of Health

From: Julie Kotchevar, Ph.D., Secretary State Board of Health

Re: Consideration and adoption of proposed regulation amendment(s) to Nevada Administrative Code (NAC) 449, "Medical Facilities and Other Related Entities", LCB File No. R133-18.

PURPOSE OF AMENDMENT

The sections of the proposed regulations addressing the "CARA plan of care" in the proposed regulations are being moved forward to bring Nevada into compliance with "*The Comprehensive Addiction and Recovery Act (CARA), Public Law 114-198*" which was signed into federal law on July 22, 2016. Sec. 503 of CARA - Infant Plan of Safe Care: "*Requires HHS to produce information concerning best practices on developing plans for the safe care of infants born with substance use disorders or showing withdrawal symptoms. This section also requires that a State plan addresses the health and SUD treatment needs of the infant, among others.*" The acronym, SUD, means substance use disorder. The purpose of sections 2 to 8 of the proposed 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 proposed 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 proposed regulations requiring certain hospitals to be primarily engaged in providing inpatient services, 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 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.

SUMMARY OF CHANGES TO NEVADA ADMINISTRATIVE CODE (NAC)

The Board of Health last revised regulations to the hospitals section of NAC Chapter 449 in 2017. The Board of Health last revised regulations to the obstetric care section of NAC Chapter 449 in 2016.

The proposed changes to NAC Chapter 449, LCB File No. R133-18, include the following:

- Health care providers that deliver or provide medical services to an infant in a hospital or obstetric center and know or have reasonable cause to believe that the infant has been affected by a fetal alcohol spectrum disorder or prenatal substance abuse or is experiencing withdrawal symptoms resulting from in utero drug exposure, the hospital or obstetric center shall ensure a comprehensive addiction and recovery act (CARA) plan of care is in place prior to or upon the infant's discharge.
- Requires a copy of the CARA plan of care to be provided to each parent or legal guardian of the infant, or both, if applicable, upon discharge, and to the Division within 24 hours after the infant is discharged from the hospital or obstetric center and requires the Division to monitor the CARA plan of care.
- All hospitals (with specific exceptions) must be primarily engaged in providing the services described in 42 U.S.C. § 1395x(e)(1) to inpatients.

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;"

• Hospital operators (with specific exceptions) must within 12 months of obtaining a state license submit proof to the Division of Public and Behavioral Health that the hospital has been deemed to meet the

Centers for Medicare and Medicaid Services standards by an accrediting organization approved by the Centers for Medicare and Medicaid Services. This accreditation must be maintained so long as the hospital is licensed in Nevada. (This change does not apply to hospitals currently licensed by the state that obtained initial licensure on or prior to adoption of these regulations.)

- Provide for the security of, and accountability for, the personal effects of a patient who is transferred to another facility.
- Redefines NAC 449.289 "Inpatient" and NAC 449.297 "Outpatient."

An errata is being moved forward to change the name from "plan of safe care" as currently noted in the proposed regulations, to CARA Plan of Care, to make it clear this plan of care is related to the Comprehensive Addiction and Recovery Act and to avoid confusion with another plan that uses a similar name.

POSSIBLE OUTCOME IF PROPOSED AMENDMENT IS NOT APPROVED

If the proposed amendments are not approved, the Division may not be in compliance with federal regulations related to the development and monitoring of a plan of safe care for an infant born and identified as being affected by substance abuse or withdrawal symptoms, or a Fetal Alcohol Spectrum Disorder.

Smaller hospitals may open in urban areas without meeting the additional requirements outlined in the proposed regulations which may allow the smaller hospitals to function more like an outpatient emergency services facility than a hospital. This may result in a burden on full service hospitals who may end up taking patient transfers from these smaller hospitals not capable of meeting the full needs of patients and/or resulting in financial difficulties for certain patients if medical insurance is not accepted.

APPLICABILITY OF PROPOSED AMENDMENT

Sections 2 to 8 of the proposed regulations apply to all hospitals and obstetric centers that deliver or provide medical services to an infant.

Section 9 applies to all hospitals except a psychiatric hospital, rural hospital, critical access hospital, hospitals that have distinct part skilled nursing or nursing facilities, and do not apply to a hospital that was initially licensed on or before the effective date of the proposed regulation which has been licensed continually after that date.

Section 10 applies to all hospitals except a psychiatric hospital, rural hospital, critical access hospital, hospitals that have distinct part skilled nursing or nursing facilities, a long term acute care hospital, a state-owned hospital, a rehabilitation hospital or a hospital that was initially licensed before the effective date of the proposed regulations and have remained licensed afterwards.

Sections 12, 13, 14 and 15 apply to all licensed hospitals in Nevada.

PUBLIC COMMENT RECEIVED

An outline of opportunities for public comment follows:

Pursuant to NRS 233B.0608 (2) (a), 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). An electronic notice was sent to licensed hospitals, pending hospital and obstetric center applicants with

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information on how to provide feedback on the proposed regulations with a link to the Small Business Impact Questionnaire and to the proposed regulations on June 20, 2018. These were also posted on the Division's website.

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?	Doyouanticipateanyindirectbeneficialeffectsuponyour business?	
Yes	Yes	Yes	Yes	
No	No	No	No	

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 proposed 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, including noting sections 9 to 15 were important updates and that passage of the proposed regulations was supported, 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.

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

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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, as noted in the errata.

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.

STAFF RECOMMENDATION

Staff recommends the State Board of Health adopt the proposed regulation amendments to Nevada Administrative Code (NAC) 449, "Medical Facilities and Other Related Entities, LCB File No. R133-18 with the errata.

<u>PRESENTER</u> Leticia Metherell, Health Program Manager III

Enclosures

PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R133-18

September 7, 2018

EXPLANATION - Matter in *italics* is new; matter in brackets [omitted material] is material to be omitted.

AUTHORITY: §§1-15, NRS 439.200 and 449.0302.

A REGULATION relating to health care; requiring a plan of safe care to be established for an infant affected by prenatal substance abuse in a medical facility; requiring the Division of Public and Behavioral Health of the Department of Health and Human Services to take certain actions regarding the plan of safe care; requiring certain hospitals to be primarily engaged in providing inpatient services and accredited as meeting the prerequisite conditions for participation in Medicare; clarifying which patients are considered inpatients; requiring a hospital to submit to the Division proof of compliance with certain requirements concerning the provision of care and the transfer of patients; prescribing certain requirements relating to the referral of a patient for outpatient services or the transfer of a patient to another facility; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

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. (42 U.S.C. § 5106(b)(2)(B)(iii)) Sections 2-6 of this regulation define terms used in provisions relating to plans of safe care. Section 7 of this regulation requires a provider of health care who delivers or provides services to 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 in a medical facility to establish a plan of safe care for the infant and prescribes the required contents of a plan of safe care. Section 7 also requires a medical facility to provide a copy of the plan of safe care to the parents or legal guardian of the infant and the Division of Public and Behavioral Health of the Department of Health and Human Services. Section 8 of this regulation requires the Division to: (1) monitor the implementation of each plan of safe care to ensure that the infant and his or her family are receiving appropriate services; and (2) provide a copy of a plan of safe care to an agency which provides child welfare services upon request. Additionally, section 8 provides for the confidentiality and safe maintenance of a plan of safe care and any associated information.

Existing federal law requires a hospital that participates in Medicare to be primarily engaged in providing certain services to inpatients. (42 U.S.C. §1396x(e)) Section 9 of this regulation: (1) requires a hospital, with certain exceptions, to be primarily engaged in providing those services to inpatients; and (2) prescribes the manner in which the Division must determine whether a hospital is primarily engaged in providing those services to inpatients.

Existing federal regulations: (1) require a hospital to meet certain conditions in order to participate in Medicare; and (2) provide for the accreditation by a national accrediting organization of hospitals that meet those conditions. (42 C.F.R. §§ 488.3 and 488.4) Section 10 of this regulation requires a hospital, with certain exceptions, to be accredited by such an organization. Section 10 also requires a hospital that is accredited, regardless of whether the hospital is required to be accredited, to: (1) submit to the Division proof of such accreditation at prescribed times; and (2) notify the Division if the hospital ceases to be accredited.

Section 12 of this regulation amends the definition of the term "inpatient" to mean a person who is admitted to a hospital for purposes of diagnosis or treatment and who: (1) is expected, at the time of admission, to receive care or occupy a bed at the hospital at midnight on at least 2 consecutive days; or (2) actually receives care or occupies a bed at the hospital at midnight on at least 2 consecutive days. Section 13 of this regulation makes a conforming change.

Existing regulations require a hospital to develop and carry out policies and procedures to ensure that emergency services and medical care are provided in accordance with certain federal and state requirements. Existing regulations also require a hospital that does not have its own long-term facility to have transfer agreements with long-term facilities. (NAC 449.331) Section 14 of this regulation requires a hospital to submit with each application for initial licensure or renewal of a license an attestation under penalty of perjury compliance with those requirements.

Existing regulations require a hospital that refers a patient for outpatient services or transfers a patient to another facility to share necessary medical information about the patient with the receiving service or facility. (NAC 449.332) Section 15 of this regulation requires such a hospital to also share necessary administrative information with the receiving service or other facility or make necessary administrative and medical information available to the receiving service or other facility. Section 15 also requires a hospital that refers a patient for outpatient services or transfers a patient to another facility to provide for the security of and accountability for the personal effects of the patient.

Section 1. Chapter 449 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 10, inclusive, of this regulation.

Sec. 2. As used in sections 2 to 8, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 3 to 6, inclusive, of this regulation have the meanings ascribed to them in those sections.

Sec. 3. "Infant" means a child who is less than 1 year of age.

Sec. 4. "Medical facility" means a hospital or an obstetric center.

Sec. 5. "Plan of safe care" means a plan that is established pursuant to section 7 of this regulation for the care of an infant who has a fetal alcohol spectrum disorder, has been affected by prenatal substance abuse or is experiencing symptoms of withdrawal from a substance as a result of exposure to the substance in utero.

Sec. 6. "Provider of health care" has the meaning ascribed to it in NRS 629.031.

Sec. 7. 1. A provider of health care who delivers or provides medical services to an infant in a medical facility and who, in his or her professional capacity, knows or has reasonable cause to believe that the infant was born with a fetal alcohol spectrum disorder, is affected by substance abuse or is experiencing symptoms of withdrawal from a drug as a result of exposure to the drug in utero, shall ensure that a plan of safe care is established for the infant before the infant is discharged from the medical facility.

2. A plan of safe care must be completed using the form prescribed by the Division and include, without limitation:

(a) Measures to ensure the immediate safety of the infant;

(b) Measures to address the needs of the infant and his or her family or caregiver for substance abuse treatment and health care;

(c) Measures to ensure that the infant and his or her family or caregiver receive any necessary services, including, without limitation, referrals to appropriate providers of such services; and

(d) Any other information necessary to ensure that the needs of the infant are met.

3. When an infant is discharged from a medical facility, the medical facility shall provide a copy of any plan of safe care established pursuant to subsection 1 to:

(a) Each parent or legal guardian of the infant to whom the plan of safe care pertains, or both, if applicable; and

(b) The Division, within 24 hours.

Sec. 8. 1. The Division shall:

(a) 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 this regulation to ensure that the infant to whom the plan pertains and his or her family or caregiver are receiving appropriate services; and

(b) Provide a copy of a plan of safe care in the possession of the Division to an agency which provides child welfare services upon request.

2. Except as otherwise provided in this section and NRS 239.0115, a plan of safe care in the possession of the Division or an agency which provides child welfare services and any information associated with such a plan of safe care is confidential, not subject to subpoena or discovery and not subject to inspection by the general public.

3. The Division and an agency which provides child welfare services shall ensure that a plan of safe care in the possession of the Division or the agency which provides child welfare services, as applicable, and any information associated with such a plan of safe care is:

(a) Adequately protected from fire, theft, loss, destruction, other hazards and unauthorized access; and

(b) Stored in a manner that protects the security and confidentiality of the information.

4. As used in this section, "agency which provides child welfare services" has the meaning ascribed to it in NRS 432B.030.

Sec. 9. 1. A hospital must be primarily engaged in providing the services described in 42 U.S.C. § 1395x(e)(1) to inpatients, unless the hospital:

(a) Is a psychiatric hospital or rural hospital;

(b) Has been certified as a critical access hospital by the Secretary of Health and Human Services pursuant to 42 U.S.C. § 1395i-4(e); or

(c) Contains a distinct part skilled nursing facility or nursing facility, as defined in 42 C.F.R. § 483.5.

2. Except as otherwise provided in subsections 3 and 4, the Division shall determine whether a hospital meets the requirements of subsection 1 based on a totality of the circumstances.

3. Except as otherwise provided in subsection 4, the Division will deem a hospital to be in compliance with subsection 1 if the hospital:

(a) Has 20 or fewer inpatient beds;

(b) Has been licensed and operating for less than 12 months; and

--5--LCB Draft of Proposed Regulation R133-18 (c) Contains a number of inpatient beds that is equal to or greater than the capacity for patients in the emergency room at the hospital.

4. The provisions of subsection 3 do not apply to a hospital that was initially licensed on or before the effective date of this regulation and has been licensed continually after that date.

5. The Division will determine that a hospital does not meet the requirements of subsection 1 if the hospital did not maintain:

(a) A minimum average daily census of at least two inpatients, as determined pursuant to subsection 6; and

(b) An average length of stay of at least 2 days during the 12 months immediately preceding the date on which the Division evaluates the hospital, as determined pursuant to subsection 6.

6. For the purposes of this section:

(a) Average daily census must be calculated by dividing the sum for the evaluation period of the number of inpatients in the hospital at midnight of each day of the evaluation period by the number of days in the evaluation period.

(b) Average length of stay must be calculated by dividing the total number of inpatient hospital days in an evaluation period by the number of discharges from the hospital in the evaluation period. As used in this paragraph, "inpatient hospital day" means:

(1) The day on which a patient is admitted to a hospital;

(2) The day on which a patient is discharged from a hospital, including, without limitation, the day on which a patient dies; and

(3) Each day after the day on which a patient is admitted to a hospital and before the patient is discharged.

Sec. 10. 1. A hospital must be accredited by an approved national accrediting organization unless the hospital:

(a) Is a psychiatric hospital or rural hospital;

(b) Has been certified as a critical access hospital by the Secretary of Health and Human Services pursuant to 42 U.S.C. § 1395i-4(e);

(c) Contains a distinct part skilled nursing facility or a nursing facility, as defined in 42 C.F.R. § 483.5;

(d) Is a hospital described in 42 U.S.C. § 1395ww(d)(1)(B)(iv) and accepts payment through Medicare;

(e) Is owned by this State or a political subdivision thereof;

(f) Is licensed only for rehabilitation beds; or

(g) Was initially licensed before the effective date of this regulation and has been licensed continually after that date.

2. A hospital that is required to comply with the requirements of subsection 1 shall submit to the Division proof of such compliance:

(a) Not later than 12 months after obtaining an initial license; and

(b) With each application for renewal submitted pursuant to NAC 449.0116.

3. A hospital that is not required to comply with the requirements of subsection 1 but is accredited by an approved national accrediting organization shall submit to the Division proof of such accreditation with each application for renewal.

4. If a hospital that is accredited by an approved national accrediting organization ceases to be so accredited, the hospital must immediately notify the Division.

5. As used in this section, "approved national accrediting organization" means a national accrediting organization, as defined in 42 C.F.R. § 488.1, that has been approved by the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services pursuant to 42 C.F.R. § 488.5.

Sec. 11. NAC 449.279 is hereby amended to read as follows:

449.279 As used in NAC 449.279 to 449.394, inclusive, *and sections 9 and 10 of this regulation,* unless the context otherwise requires, the words and terms defined in NAC 449.285 to 449.300, inclusive, have the meanings ascribed to them in those sections.

Sec. 12. NAC 449.289 is hereby amended to read as follows:

449.289 "Inpatient" means a person who has been formally admitted into a hospital for diagnosis or treatment [.] *and*:

1. Is expected, at the time of admission, to receive care or occupy a bed at the hospital at midnight on at least 2 consecutive days; or

2. Actually receives care or occupies a bed at the hospital at midnight on at least 2 consecutive days.

Sec. 13. NAC 449.297 is hereby amended to read as follows:

449.297 "Outpatient" means a person who has been registered or accepted for care in a hospital but who [has not been formally admitted as] is not an inpatient. [, and who does not remain in the hospital for more than 48 hours.]

Sec. 14. NAC 449.331 is hereby amended to read as follows:

449.331 1. A hospital shall develop and carry out policies and procedures to ensure that emergency services and medical care are provided in accordance with NRS 439B.410 and 450B.790 and 42 C.F.R. § 489.24 and to ensure compliance with the provisions of NRS 450B.795.

2. All general hospitals not having their own long-term facility shall have transfer agreements with long-term care facilities. Transfer agreements between facilities must be in writing and on file at each facility concerned. The agreements must provide for:

(a) The transfer of patients between facilities whenever the need for transfer is medically determined; and

(b) The exchange of appropriate medical and administrative information between facilities.

3. In addition to the application required by NAC 449.011 or 449.0116, as applicable, a hospital applying for initial licensure or the renewal of its license shall submit to the Division an attestation under penalty of perjury that the hospital is in compliance with the requirements of this section.

Sec. 15. NAC 449.332 is hereby amended to read as follows:

449.332 1. A hospital shall:

(a) Have a process for discharge planning that applies to all inpatients; and

(b) Develop and carry out policies and procedures regarding the process for discharge planning.

2. The process for discharge planning must include the participation of registered nurses, social workers or other personnel qualified, through education or experience, to perform discharge planning.

3. A hospital shall, at the earliest possible stage of hospitalization, identify each patient who is likely to suffer adverse health consequences upon discharge if the patient does not receive adequate discharge planning. The hospital shall provide for an evaluation of the needs related to discharge planning of each patient so identified.

4. An evaluation of the needs of a patient relating to discharge planning must include, without limitation, consideration of:

(a) The needs of the patient for postoperative services and the availability of those services;

(b) The capacity of the patient for self-care; and

(c) The possibility of returning the patient to a previous care setting or making another appropriate placement of the patient after discharge.

5. If the evaluation of a patient relating to discharge planning indicates a need for a discharge plan, a discharge plan must be developed under the supervision of a registered nurse, social worker or other person qualified to perform discharge planning.

6. An evaluation of a patient relating to discharge planning and a discharge plan for the patient may be requested by the patient, a physician, a member of the family of the patient or the guardian of the patient, if any.

7. If a hospital finds that a patient does not need a discharge plan, the attending physician may still request a discharge plan for the patient. If the attending physician makes such a request, the physician shall collaborate as much as necessary with the hospital staff in the development of the discharge plan.

8. Activities related to discharge planning must be conducted in a manner that does not contribute to delays in the discharge of the patient.

9. The evaluation of the needs of a patient relating to discharge planning and the discharge plan for the patient, if any, must be documented in his or her medical record.

10. The discharge plan must be discussed with the patient or the person acting on behalf of the patient.

11. The patient, members of the family of the patient and any other person involved in caring for the patient must be provided with such information as is necessary to prepare them for the posthospital care of the patient.

12. If, during the course of a patient's hospitalization, factors arise that may affect the needs of the patient relating to his or her continuing care or current discharge plan, the needs of the patient must be reassessed and the plan, if any, must be adjusted accordingly.

13. A hospital shall arrange for the initial implementation of the discharge plans of its patients.

14. If identified in a discharge plan, referral of a patient to outpatient services or transfer of the patient to another facility must be accomplished in a manner that meets the identified needs of the patient, including [the sharing of], without limitation:

(a) Upon the referral or transfer, necessary sharing of administrative and medical information about the patient with the receiving service or other facility [.] or making such information available to the service or other facility; and

(b) Providing for the security of and accountability for the personal effects of the patient.

Errata – LCB File No. R133-18.

Blue italic = Proposed language found in LCB File No. R133-18

Green italic = New language proposed in Errata.

[Red italic bold bracketed strikethrough] = Proposed omission in Errata to current LCB File No. R133-18 draft.

Sec. 5. "[*Plan of safe care*] CARA Plan of Care" means a plan that is established pursuant to section 7 of this regulation for the care of an infant who has a fetal alcohol spectrum disorder, has been affected by prenatal substance abuse or is experiencing symptoms of withdrawal from a substance as a result of exposure to the substance in utero.

Sec. 7. 1. A provider of health care who delivers or provides medical services to an infant in a medical facility and who, in his or her professional capacity, knows or has reasonable cause to believe that the infant was born with a fetal alcohol spectrum disorder, is affected by substance abuse or is experiencing symptoms of withdrawal from a drug as a result of exposure to the drug in utero, shall ensure that a [plan of safe care] CARA Plan of Care is established for the infant before the infant is discharged from the medical facility.

2. A [plan of safe care] CARA Plan of Care must be completed using the form prescribed by the Division and include, without limitation:

(a) Measures to ensure the immediate safety of the infant;

(b) Measures to address the needs of the infant and his or her family or caregiver for substance abuse treatment and health care;

(c) Measures to ensure that the infant and his or her family or caregiver receive any necessary services, including, without limitation, referrals to appropriate providers of such services; and (d) Any other information necessary to ensure that the needs of the infant are met.

3. When an infant is discharged from a medical facility, the medical facility shall provide a copy of any [plan of safe care] CARA Plan of Care established pursuant to subsection 1 to:
(a) Each parent or legal guardian of the infant to whom the [plan of safe care] CARA Plan of Care pertains, or both, if applicable; and
(b) The Division, within 24 hours.

Sec. 8. 1. The Division shall:

(a) Monitor, in accordance with 42 U.S.C. § 5106a(b)(2)(B)(iii)(II), the implementation of each [plan of safe care] CARA Plan of Care that it receives pursuant to section 7 of this regulation to ensure that the infant to whom the plan pertains and his or her family or caregiver are receiving appropriate services; and

(b) Provide a copy of a [plan of safe care] CARA Plan of Care in the possession of the Division to an agency which provides child welfare services upon request.

2. Except as otherwise provided in this section and NRS 239.0115, a [plan of safe care] CARA Plan of Care in the possession of the Division or an agency which provides child welfare services and any information associated with such a [plan of safe care] CARA Plan of Care is confidential, not subject to subpoena or discovery and not subject to inspection by the general public.

3. The Division and an agency which provides child welfare services shall ensure that a [plan of safe care] CARA Plan of Care in the possession of the Division or the agency which provides child welfare services, as applicable, and any information associated with such a [plan of safe care] CARA Plan of Care is:

(a) Adequately protected from fire, theft, loss, destruction, other hazards and unauthorized access; and

(b) Stored in a manner that protects the security and confidentiality of the information.

4. As used in this section, "agency which provides child welfare services" has the meaning ascribed to it in NRS 432B.030.

Rationale:

The change of name from the plan of safe care to the CARA plan of care is being made to avoid confusion with another plan that uses a similar name.

SMALL BUSINESS IMPACT STATEMENT 2018 PROPOSED AMENDMENTS TO NEVADA ADMINISTRATIVE CODE (NAC) 449

The Division of Public and Behavioral Health (DPBH) has determined that the proposed amendment should not have an adverse fiscal impact on small businesses and should not prevent the formation, operation or expansion of a small business in Nevada.

A small business is defined in Nevada Revised Statutes NRS 233B as a "business conducted for profit which employs fewer than 150 full-time or part-time employees."

This small business impact statement is made pursuant to NRS 233B.0608 (3) and complies with the requirements of NRS 233B.0609. As required by NRS 233B.0608(3), this statement identifies the methods used by the agency in determining the impact of the proposed regulation on a small business in sections 1, 2, 3, and 4 below and provides the reasons for the conclusions of the agency in section 8 below followed by the certification by the person responsible for the agency.

Background

The sections of the proposed regulations addressing the "CARA plan of care" in the proposed regulations are being moved forward to bring Nevada into compliance with "The Comprehensive Addiction and Recovery Act (CARA), Public Law 114-198" which was signed into federal law on July 22, 2016. Sec. 503 of CARA - *Infant Plan of Safe Care*: "Requires HHS to produce information concerning best practices on developing plans for the safe care of infants born with substance use disorders or showing withdrawal symptoms. This section also requires that a State plan addresses the health and SUD treatment needs of the infant, among others."

The remaining sections of the proposed regulations requiring certain hospitals to be primarily engaged in providing inpatient services, to be deemed to meet Centers for Medicare and Medicaid Services standards by an accrediting organization approved by the Centers for Medicare and Medicaid Services 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 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.

The major provisions of the proposed regulations provide for the following:

• Health care providers that deliver or provide medical services to an infant in a hospital or obstetric center and know or have reasonable cause to believe that the infant has been affected by a fetal alcohol spectrum disorder or prenatal substance abuse or is experiencing withdrawal symptoms resulting from in utero drug exposure the hospital or obstetric center shall ensure a comprehensive addiction and recovery act (CARA) plan of care is in place prior to or upon the infant's discharge.

- Requires the CARA plan of care to be submitted to the Division within 24 hours after the infant is discharged from the hospital or obstetric center and requires the Division to monitor the CARA plan of care.
- All hospitals (with specific exceptions) must be primarily engaged in providing inpatient services.
- Hospital operators (with specific exceptions) must within 12 months of obtaining a state license submit proof to the Division of Public and Behavioral Health that the hospital has been deemed to meet the Centers for Medicare and Medicaid Services standards by an accrediting organization approved by the Centers for Medicare and Medicaid Services. This accreditation must be maintained so long as the hospital is licensed in Nevada. (This change does not apply to hospitals currently licensed by the state that obtained initial licensure on or prior to adoption of these regulations.)
- Provide for the security of, and accountability for, the personal effects of a patient who is transferred to another facility.
- Redefines NAC 449.289 "Inpatient" and NAC 449.297 "Outpatient"

1) A description of the manner in which comment was solicited from affected small businesses, a summary of their response and an explanation of the manner in which other interested persons may obtain a copy of the summary.

Pursuant to NRS 233B.0608 (2)(a), the Division of Public and Behavioral Health (DPBH) has requested input from Nevada's licensed hospitals. In addition, as there currently are no licensed obstetric centers, it was sent to the only pending applicant to open an obstetric center. The Division has made a concerted effort to determine whether the proposed regulations are likely to impose an economic burden upon a small business.

Notice was sent to all hospitals licensed by the Division and one pending obstetric center on June 20, 2018, requesting that all interested individuals complete the small business impact questionnaire. An email notice with a link to the small business impact questionnaire and proposed regulations was sent. The proposed regulations were also posted on DPBH'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 (0 responses were received out of 72 small business impact questionnaires distributed)			
Will a specific	Will the regulation	Do you	Do you anticipate any indirect
regulation have	(s) have any	anticipate any	beneficial effects upon your
an adverse	beneficial effect	indirect adverse	business?

economic effect upon your business?	upon your business?	effects upon your business?	
Yes	Yes	Yes	Yes
No	No	No	No

No small business impact questionnaire responses were returned to the Division.

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:

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: Imetherell@health.nv.gov

2) Describe the manner in which the analysis was conducted.

An analysis was conducted by a Health Program Manager III. No small business impact questionnaires were returned to the Division. No input was received indicating that the proposed regulations would be a financial burden. For items that may cause a fiscal impact, such as requiring certain hospitals to be deemed to meet Centers for Medicare and Medicaid Services standards, would not apply to rural hospitals. This would remove the potential negative fiscal impact to rural hospitals which generally tend to be smaller than hospitals found in large urban areas.

This information was then used to complete this small business impact statement including the conclusion on the impact of the proposed regulation on a small business found in number 8.

3) The estimated economic effect of the proposed regulation on the small business which it is to regulate including, without limitation both adverse and beneficial effects and both direct and indirect effects.

Direct Beneficial Effects: There are no anticipated direct beneficial financial effects to small businesses.

Indirect Beneficial Effects: There are no anticipated indirect beneficial financial effects to small businesses.

Direct Adverse Effects: There are no anticipated direct adverse financial effects to small businesses.

Indirect Adverse Effects: There are no anticipated indirect adverse financial effects to small businesses.

4) Provide a description of the methods that the agency considered to reduce the impact of the proposed regulation on small businesses and a statement regarding whether the agency actually used any of those methods.

The Division of Public and Behavioral Health has identified and used methods to reduce the impact of the proposed regulations on small businesses including distribution of the small business impact questionnaire to all licensed hospitals by the Division and one pending obstetric center, so they could provide input on how the proposed regulations may impact their business. The Division did implement the measure it identified to reduce the burden on small businesses by exempting rural hospitals, which tend to be smaller than larger urban hospitals, from meeting requirements that may produce an adverse financial impact.

A public workshop will also be held allowing for further input by stakeholders regarding the proposed regulations and their impact on industry. These comments will be taken into consideration for possible further revisions to the regulations to reduce the economic impact on programs.

5) The estimated cost to the agency for enforcement of the proposed regulation.

The workload created by these proposed 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 proposed regulations is anticipated at this time.

6) If the proposed regulation provides a new fee or increases an existing fee, the total annual amount DPBH expects to collect and the manner in which the money will be used. The proposed regulations do not provide for a new fee or increase an existing fee that would be collected by the Division.

7) An explanation of why any duplicative or more stringent provisions than federal, state or local standards regulating the same activity are necessary.

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 SUD treatment needs of the infant; therefore, the proposed 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.

8) Provide a summary of the reasons for the conclusions of the agency regarding the impact of a regulation on small businesses.

The reasons for the Division's conclusion on the impact of the proposed regulations on small businesses is based on the analysis conducted in number two. The conclusion is the proposed regulations should not have a negative financial impact on small businesses.

Certification by Person Responsible for the Agency

I, Julie Kotchevar, Administrator of the Division of Public and Behavioral Health certify to the best of my knowledge or belief, a concerted effort was made to determine the impact of the proposed regulation on small businesses and the information contained in this statement was prepared properly and is accurate.

Signature_ Mutatitue Date: 89-18

NOTICE OF PUBLIC HEARING

Intent to Adopt Regulations (LCB File No. R133-18)

NOTICE IS HEREBY GIVEN that the State Board of Health will hold a public hearing to consider amendments to Chapter 449 of Nevada Administrative Code (NAC), Medical Facilities and Other Related Entities, LCB File No. R133-18. This public hearing is to be held in conjunction with the State Board of Health meeting on December 7, 2018.

The State Board of Health will be conducted via videoconference beginning at 9:00 a.m. on Friday, December 7, 2018 at the following locations:

The proposed changes to NAC 449, LCB File No. R133-18, include the following:

- Health care providers that deliver or provide medical services to an infant in a hospital or obstetric center and know or have reasonable cause to believe that the infant has been affected by a fetal alcohol spectrum disorder or prenatal substance abuse or is experiencing withdrawal symptoms resulting from in utero drug exposure, the hospital or obstetric center shall ensure a comprehensive addiction and recovery act (CARA) plan of care is in place prior to or upon the infant's discharge.
- Requires a copy of the CARA plan of care to be provided to each parent or legal guardian of the infant, or both, if applicable, upon discharge, and to the Division within 24 hours after the infant is discharged from the hospital or obstetric center and requires the Division to monitor the CARA plan of care.
- All hospitals (with specific exceptions) must be primarily engaged in providing the services described in 42 U.S.C. § 1395x(e)(1) to inpatients.
- Hospital operators (with specific exceptions) must within 12 months of obtaining a state license submit proof to the Division of Public and Behavioral Health that the hospital has been deemed to meet the Centers for Medicare and Medicaid Services standards by an accrediting organization approved by the Centers for Medicare and Medicaid Services. This accreditation must be maintained so long as the hospital is licensed in Nevada. (This change does not apply to hospitals currently licensed by the state that obtained initial licensure on or prior to adoption of these regulations.)

- Provide for the security of, and accountability for, the personal effects of a patient who is transferred to another facility.
- Redefines NAC 449.289 "Inpatient" and NAC 449.297 "Outpatient."

1. Anticipated effects on the business which NAC 449 regulates:

- A. Adverse effects: There are no anticipated adverse financial effects to small businesses.
- B. Beneficial: There are no anticipated beneficial financial effects to small businesses.
- C. Immediate: There are no anticipated immediate financial effects to small businesses.
- D. *Long-term:* There are no anticipated long-term financial effects to small businesses. 2. Anticipated effects on the public:
 - A. Adverse: There are no anticipated adverse effects to the public.

B. *Beneficial:* 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 the safety and needs of the infant are met.

C. *Immediate*: 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.

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

3. No costs are anticipated to the Division of Public and Behavioral Health for enforcement of the proposed regulations. The workload created by these proposed 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 proposed regulations is anticipated at this time.

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 proposed 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.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence in excess of two typed, 8-1/2" x 11" pages must

submit the material to the Board's Secretary, Julie Kotchevar, to be received no later than November 29, 2018 at the following address:

Secretary, State Board of Health Division of Public and Behavioral Health 4150 Technology Way, Suite 300 Carson City, NV 89706

Written comments, testimony, or documentary evidence in excess of two typed pages will not be accepted at the time of the hearing. The purpose of this requirement is to allow Board members adequate time to review the documents.

A copy of the notice and proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

Nevada Division of Public and Behavioral Health
727 Fairview Drive, Suite E
Carson City, NV 89701

Nevada Division of Public and Behavioral Health 4220 S. Maryland Parkway, Suite 810, Building D Las Vegas, NV 89119 Nevada State Library 100 Stewart Street Carson City, NV 89701

A copy of the regulations and small business impact statement can be found on-line by going to: <u>http://dpbh.nv.gov/Reg/HealthFacilities/State_of_Nevada_Health_Facility_Regulation_Public_Workshops/</u>

A copy of the public hearing notice can also be found at Nevada Legislature's web page: <u>https://www.leg.state.nv.us/App/Notice/A/</u>

Copies may be obtained in person, by mail, or by calling the Division of Public and Behavioral Health at (775) 684-1030 in Carson City or (702) 486-6515 in Las Vegas. Copies may also be obtained from any of the public libraries listed below:

Carson City Library 900 North Roop Street Carson City, NV 89702

Clark County District Library 1401 East Flamingo Road Las Vegas, NV 89119 Page **3** of **4** Churchill County Library 553 South Main Street Fallon, NV 89406

Douglas County Library 1625 Library Lane Minden, NV 89423 Elko County Library 720 Court Street Elko, NV 89801

Eureka Branch Library 80 South Monroe Street Eureka, NV 89316-0283

Humboldt County Library 85 East 5th Street Winnemucca, NV 89445-3095

Lincoln County Library 93 Maine Street Pioche, NV 89043-0330

Mineral County Library 110 1st Street Hawthorne, NV 89415-1390

Pershing County Library 1125 Central Avenue Lovelock, NV 89419-0781

Tonopah Public Library 167 Central Street Tonopah, NV 89049-0449

White Pine County Library 950 Campton Street Ely, NV 89301-1965 Esmeralda County Library Corner of Crook and 4th Street Goldfield, NV 89013-0484

Henderson District Public Library 280 South Green Valley Parkway Henderson, NV 89012

Lander County Library 625 South Broad Street Battle Mountain, NV 89820-0141

Lyon County Library 20 Nevin Way Yerington, NV 89447-2399

Pahrump Library District 701 East Street Pahrump, NV 89041-0578

Storey County Library 95 South R Street Virginia City, NV 89440-0014

Washoe County Library 301 South Center Street Reno, NV 89505-2151

Per NRS 233B.064(2), upon adoption of any regulation, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

NOTICE OF PUBLIC WORKSHOP

NOTICE IS HEREBY GIVEN that the Division of Public and Behavioral Health will hold a public workshop to consider amendments to Nevada Administrative Code (NAC) Chapter 449, LCB File No. R133-18.

The workshop will be conducted via videoconference and teleconference beginning at 2:00 PM on Tuesday, October 30, 2018, at the following locations:

Division of Public and Behavioral Health	Division of Public and Behavioral Health	
Bureau of Health Care Quality and Compliance	Bureau of Health Care Quality and Compliance	
727 Fairview Drive, Suite E	4220 South Maryland Parkway, Suite 810,	
Carson City, NV 89701	Building D	
-	Las Vegas, NV 89119	
TELECONFERENCE NUMBER: 1-877-336-1829		

These workshops will be conducted in accordance with NRS 241.020, Nevada's Open Meeting Law.

AGENDA

- 1. Introduction of workshop process
- 2. Public comment on proposed amendments to Nevada Administrative Code Chapter 449, LCB File No. R133-18.
- 3. Public Comment

The proposed changes found in LCB File No. R133-18 will revise Chapter 449 of the Nevada Administrative Code and are being proposed in accordance with §§1-15, NRS 439.200 and 449.0302.

The proposed regulations provide provisions for the following:

- Health care providers that deliver or provide medical services to an infant in a hospital or obstetric center and know or have reasonable cause to believe that the infant has been affected by a fetal alcohol spectrum disorder or prenatal substance abuse or is experiencing withdrawal symptoms resulting from in utero drug exposure, the hospital or obstetric center shall ensure a comprehensive addiction and recovery act (CARA) plan of care is in place prior to or upon the infant's discharge.
- Requires a copy of the CARA plan of care to be provided to each parent or legal guardian of the infant, or both, if applicable, upon discharge, and to the Division within 24 hours after the infant is discharged from the hospital or obstetric center and requires the Division to monitor the CARA plan of care.
- All hospitals (with specific exceptions) must be primarily engaged in providing the services described in 42 U.S.C. § 1395x(e)(1) to inpatients.
- Hospital operators (with specific exceptions) must within 12 months of obtaining a state license submit proof to the Division of Public and Behavioral Health that the hospital has been deemed to meet the Centers for Medicare and Medicaid Services standards by an accrediting organization approved by the Centers for Medicare and Medicaid Services. This accreditation must be maintained so long as the hospital is licensed in Nevada. (This change does not apply to hospitals currently licensed by the state that obtained initial licensure on or prior to adoption of these regulations.)
- Provide for the security of, and accountability for, the personal effects of a patient who is transferred to another facility.
- Redefines NAC 449.289 "Inpatient" and NAC 449.297 "Outpatient."

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence may submit the material to Leticia Metherell, Health Program Manager at the following address:

Division of Public and Behavioral Health 727 Fairview Drive, Suite E Carson City, NV 89701 <u>Imetherell@health.nv.gov</u> (E-mail) 775-684-1073 (FAX)

Members of the public who require special accommodations or assistance at the workshops are required to notify Leticia Metherell, Health Program Manager, in writing to the Division of Public and Behavioral Health, 727 Fairview Drive, Suite E, Carson City, Nevada, 89701, or by calling (775) 684-1030 at least five (5) working days prior to the date of the public workshop.

You may contact Leticia Metherell, Health Program Manager, by calling 775-684-1045 for further information on the proposed regulations or how to obtain copies of the supporting documents.

A copy of the notice and the proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

Division of Public and Behavioral Health 727 Fairview Drive, Suite E Carson City, NV Division of Public and Behavioral Health 4220 S. Maryland Parkway, Suite 810, Bldg D Las Vegas, NV

Nevada State Library and Archives 100 Stewart Street Carson City, NV

A copy of the regulations and small business impact statement can be found on the Division of Public and Behavioral Health's web page:

http://dpbh.nv.gov/Reg/HealthFacilities/State_of_Nevada_Health_Facility_Regulation_Public_Workshops/

A copy of the public workshop notice can also be found at Nevada Legislature's web page: <u>https://www.leg.state.nv.us/App/Notice/A/</u>

A copy of this notice has been posted at the following locations:

- 1. Division of Public and Behavioral Health, 4150 Technology Way, First Floor Lobby, Carson City
- 2. Nevada State Library and Archives, 100 Stewart Street, Carson City
- 3. Legislative Building, 401 S. Carson Street, Carson City
- 4. Grant Sawyer Building, 555 E. Washington Avenue, Las Vegas
- 5. Washoe County District Health Department, 9TH and Wells, Reno

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Douglas County Library 1625 Library Lane Minden, NV 89423

Esmeralda County Library Corner of Crook and 4th Street Goldfield, NV 89013-0484

Henderson District Public Library 280 South Water Street Henderson, NV 89105

Lander County Library 625 South Broad Street Battle Mountain, NV 89820-0141

Lyon County Library 20 Nevin Way Yerington, NV 89447-2399

Pahrump Library District 701 East Street Pahrump, NV 89041-0578

Storey County Library 95 South R Street Virginia City, NV 89440-0014

Washoe County Library 301 South Center Street Reno, NV 89505-2151

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