State of California
Office of Administrative Law

In re:
Department of Social Services

Regulatory Action:

Title 22, California Code of Regulations
Manual of Policies and Procedures

Adopt sections: 102425, 102426
Amend sections: 101239, 101416.5, 101419.2, 101429, 101430, 101439.1, 102352, 102417

DECISION OF DISAPPROVAL OF REGULATORY ACTION

Government Code Section 11349.3

OAL Matter Number: 2019-0702-01

OAL Matter Type: Regular (S)

SUMMARY OF REGULATORY ACTION

This regulatory action by the Department of Social Services (Department) proposed to update safe sleep requirements for infants in child care facilities. This action included supervision requirements for sleeping infants, specified safe sleep equipment, and proposed to include an Individual Infant Sleeping Plan to be maintained in each infant's file.

DECISION

On July 2, 2019, the Department submitted the above-referenced regulatory action to the Office of Administrative Law (OAL) for review. On August 14, 2019, OAL notified the Department of the disapproval of this regulatory action. OAL disapproved the regulatory action because the Department failed to comply with the clarity and necessity standards of Government Code section 11349.1. Additionally, the Department failed to follow all required procedures under the California Administrative Procedure Act (APA). This Decision of Disapproval of Regulatory Action explains the reasons for OAL's action.

DISCUSSION

The Department's regulatory action must satisfy requirements established by the part of the APA that governs rulemaking by a state agency. Any regulation adopted, amended, or repealed by a state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure, is subject to the APA unless a statute expressly exempts the regulation

from APA coverage. (Gov. Code, sec. 11346.) No exemption applies to the present regulatory action under review.

Before any regulation subject to the APA may become effective, the regulation is reviewed by OAL for compliance with the procedural requirements of the APA and the standards for administrative regulations in Government Code section 11349.1. Generally, to satisfy the APA standards, a regulation must be legally valid, supported by an adequate record, and easy to understand. In this review, OAL is limited to the rulemaking record and may not substitute its judgment for that of the rulemaking agency with regard to the substantive content of the regulation. This review is an independent check on the exercise of rulemaking powers by executive branch agencies intended to improve the quality of regulations that implement, interpret, and make specific statutory law, and to ensure that the public is provided with a meaningful opportunity to comment on regulations before they become effective.

1. Clarity Standard

In adopting the APA, the Legislature found that the language of many regulations was unclear and confusing to persons who must comply with the regulations. (Gov. Code, sec. 11340, subd. (b).) Government Code section 11349.1, subdivision (a)(3), requires that OAL review all regulations for compliance with the clarity standard. Government Code section 11349, subdivision (c), defines "clarity" to mean: "written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them."

The clarity standard is further defined in section 16 of title 1 of the California Code of Regulations (CCR), OAL's regulation on "clarity," which provides the following:

> In examining a regulation for compliance with the "clarity" requirement of Government Code section 11349.1, OAL shall apply the following standards and presumptions:
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> (a) A regulation shall be presumed not to comply with the "clarity" standard if any of the following conditions exists:
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> (1) the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning; or
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> (2) the language of the regulation conflicts with the agency's description of the effect of the regulation; or
>
> (3) the regulation uses terms which do not have meanings generally familiar to those "directly affected" by the regulation, and those terms are defined neither in the regulation nor in the governing statute; or

(4) the regulation uses language incorrectly. This includes, but is not limited to, incorrect spelling, grammar or punctuation; or

(5) the regulation presents information in a format that is not readily understandable by persons "directly affected;" or

(6) the regulation does not use citation styles which clearly identify published material cited in the regulation.

(b) Persons shall be presumed to be "directly affected" if they:

(1) are legally required to comply with the regulation; or

(2) are legally required to enforce the regulation; or

(3) derive from the enforcement of the regulation a benefit that is not common to the public in general; or

(4) incur from the enforcement of the regulation a detriment that is not common to the public in general.

There are a number of provisions in the Department's proposed regulatory action that do not satisfy the clarity standard.

1.1 Section 101239 of the CCR

1.1.1 Proposed subdivision (r)

Proposed subdivision (r) states: "Fixtures, furniture, and equipment that have been banned or recalled by the United States Consumer Product Safety Commission shall not be used or on the facility's premises." Proposed subdivision (r) is unclear because the language of the regulation conflicts with the description of the effect of the regulation included in the Initial Statement of Reasons (ISOR). (Cal. Code Regs., tit. 1, sec. 16, subd. (a)(2).) Proposed subdivision (r) establishes a prohibition on the use of banned or recalled products at a child care center. The ISOR states: "This section is being adopted to require centers to only use fixtures, furniture, and equipment approved by the Commission." This statement does not accurately describe what is accomplished by the adoption of subdivision (r). Contrary to the explanation provided, proposed subdivision (r) does not require the usage of "approved" fixtures, furniture, and equipment. This regulatory language merely acknowledges that fixtures, furniture, and equipment may not be banned or recalled. If the Department intends to require that products be specifically approved by the United States Consumer Product Safety Commission, the text must be revised to reflect that intent. As such, proposed subdivision (r) is unclear.

1.1.2 Proposed subdivision (r)(1)

Proposed subdivision (r)(1) states:

> If the United States Consumer Product Safety Commission authorizes a correction to a banned or recalled item, proof of the correction showing it meets the new United States Consumer Product Safety Commission standards shall be maintained at the child care center and shall be available to the licensing agency for review.

Proposed subdivision (r)(1) is unclear because the language of the regulation conflicts with the description of the effect of the regulation included in the ISOR. (Cal. Code Regs., tit. 1, sec. 16, subds. (a)(2).) Regarding this subdivision, the ISOR declares: "Banned and recalled items shall be removed from the facility ***unless*** the [Child Care Center] has proof that the manufacturer has corrected the item, so it meets the Commission's standards." (Emphasis added.) This statement does not accurately describe what is accomplished by the adoption of subdivision (r)(1). The qualification that a banned or recalled product need not be removed from the child care center if the United States Consumer Product Safety Commission has authorized a correction of the product and the manufacturer has corrected the item is not specified in regulation. If the Department intends to allow for the use of a banned or recalled product or presence of a banned or recalled product at the child care center, assuming the United States Consumer Product Safety Commission authorized a correction to the banned or recalled item and the problem has been corrected, the text must be revised to reflect that intent. As such, proposed subdivision (r)(1) is unclear.

1.2 Section 101429 of the CCR

1.2.1 Proposed subdivisions (a)(2)(B) and (C)

Proposed subdivisions (a)(2)(B) and (C) are unclear because the proposed language conflicts with the Department's description of the effect of the regulation. (Cal. Code Regs., tit. 1, sec. 16, subd. (a)(2).) Subdivisions (a)(2)(B)1. and 2. enumerate several "signs of distress" for staff to monitor while infants sleep. Subdivision (a)(2)(C) states: " If the staff person observes any of the indicators in subsections (B)1. or 2. [sic] the procedures outlined in Section 101226 shall be followed." However, the ISOR states:

> This section is necessary to ensure that caregivers can identify signs of infant distress associated with SIDS. In addition, this section creates uniformity with current requirements to notify the infant's authorized representative or seek immediate medical attention, depending on what is observed. Should the infant

experience any symptoms of distress, be in an unsafe sleeping position, or exhibit signs of overheating, the caregiver will be required to take immediate and appropriate action.

Contrary to the explanation provided, proposed subdivisions (a)(2)(B) and (C) do not "create uniformity…to notify the infant's authorized representative or seek immediate medical attention, depending on what is observed." Specifically, the regulations do not identify which "signs of distress" necessitate what kind of specific action. Subdivision (a)(2)(C) merely contains a general reference to section 101226, which enumerates a variety of notification requirements depending upon the severity of the observed health-related issue.

Additionally, the ISOR specifies that if an infant is in an unsafe sleeping position, the caregiver will be required to take immediate and appropriate action. However, the language of subdivision (a)(2)(C) is silent with respect to an infant's unsafe sleeping position. As such, proposed subdivisions (a)(2)(B) and (C) are unclear.

1.2.2 Proposed subdivision (a)(2)(D)

Proposed subdivision (a)(2)(D) reads as follows: "If any infants are sleeping in a separate room from where the staff are located, staff must be present in the designated sleeping area." This language is vague and does not present information in a format that is readily understandable to persons "directly affected." (Cal. Code Regs., tit. 1, sec. 16, subd. (a)(5).) Proposed subdivision (a)(2)(D) does not specify how many staff members must be in the designated sleeping room if infants are sleeping. It is also unclear whether staff must be present if only one infant is sleeping. If the Department intends to require a staff-infant ratio, the Department must revise the text to clarify this requirement. As written, proposed subdivision (a)(2)(D) is unclear.

1.3 Section 101430 of the CCR

1.3.1 Proposed subdivision (a)(3)(A)1.

Proposed subdivision (a)(3)(A)1. reads as follows: "The requirements set forth in section 101430(a)(3)(A) shall not apply if there is a written medical exemption for the infant's alternate sleep position completed by a licensed physician included in the Individual Infant Sleeping Plan [LIC 9227 (6/18)] containing the following criteria…." Proposed subdivision (a)(3)(A)1. uses language incorrectly and is confusing as written. (Cal. Code Regs., tit. 1, sec. 16, subd. (a)(4).) If the Department intends to require the preparation of a written medical exemption by a licensed physician to be attached to the Individual Infant Sleeping Plan, the Department must revise subdivision (a)(3)(A)1. to clearly specify this requirement. As written, the proposed language is unclear.

1.3.2 Proposed subdivision (a)(3)(A)2.a.

Proposed subdivision (a)(3)(A)2.a. states:

> If the infant is able to roll back and forth for the first time in care the provider may then fill out Section D of the Individual Infant Sleeping Plan [LIC 9227 (6/18)], notify the authorized representative, and obtain the authorized representative signature no later than the next business day.

Proposed subdivision (a)(3)(A)2.a. is unclear for two reasons. First, proposed subdivision (a)(3)(A)2.a. is unclear because the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning. (Cal. Code Regs., tit. 1, sec. 16, subd. (a)(1).) Subdivision (a)(3)(A)2.a. describes an infant's ability to "roll back and forth for the first time" as the catalyst for the completion of Section D of the Individual Infant Sleeping Plan. The regulation states that if the infant rolls back and forth for the first time while in care, such should be documented. However, by contrast, Section D of the Individual Infant Sleeping Plan requires completion when an infant "is able to roll from their back to stomach and stomach to back in care." As written, the regulation text and the Individual Infant Sleeping Plan describe two different actions by the infant, which leaves the provider with unclear instruction regarding when Section D of the form must be completed.

Second, proposed subdivision (a)(3)(A)2.a. is unclear because the proposed language conflicts with the Department's description of the effect of the regulation. (Cal. Code Regs., tit. 1, sec. 16, subd. (a)(2).) Subdivision (a)(3)(A)2.a. states that if the infant is able to roll back and forth for the first time in care, the provider *may* fill out Section D of the Individual Infant Sleeping Plan, notify the authorized representative, and obtain the authorized representative's signature. Use of the word "may" leads the reader to believe that completion of the form, notifying the authorized representative, and obtaining the authorized representative's signature are optional. However, the ISOR states:

> This section is being adopted to ***require*** licensees to share information with the authorized representative of an infant to determine whether the infant can roll over unassisted…Upon discovering that the infant has reached the developmental milestone of rolling over and back, unassisted, the licensee and the representative may agree that the infant may remain in any position that suits them after being initially placed on their back to sleep. [Emphasis added.]

If the Department intends to require providers to complete Section D of the Individual Infant Sleeping Plan, notify the authorized representative, and obtain the authorized representative's

signature after an infant rolls from their back to stomach and stomach to back while in care, the regulations must be revised to reflect this requirement. As written, proposed subdivision (a)(3)(A)2.a. is unclear.

1.4 Proposed subdivision (f)(1)(A) of section 101439.1 of the CCR

Proposed subdivision (f)(1)(A) is unclear because the regulation can be reasonably interpreted to have more than one meaning. (Cal. Code Regs., tit. 1, sec. 16, subd. (a)(1).) Proposed subdivision (f)(1)(A) states: "An infant shall not be forced to take a pacifier when put down to sleep." This language is not accompanied by a definition for the word "forced" and can be interpreted very differently by different caretakers. For example, if a caretaker provides an infant with a pacifier more than once when being put down, does this qualify as "force"? What is a reasonable number of attempts to provide an infant with a pacifier before the act qualifies as "force"? As written, subdivision (f)(1)(A) is too vague to provide a child care center with any meaningful guidance regarding the requirements being imposed and may be interpreted differently by different caretakers. As such, proposed subdivision (f)(1)(A) is unclear.

1.5 Section 102352 of the CCR

1.5.1 Proposed subdivision (o)

Proposed subdivision (o) states: "'Overnight Care' means care being provided to children through the night between the hours of 6 p.m. and 6 a.m., but not to exceed 24 hours." Proposed subdivision (o) is unclear because the proposed language conflicts with the Department's description of the effect of the regulation. (Cal. Code Regs., tit. 1, sec. 16, subd. (a)(2).) The ISOR states: "This section is necessary to establish a timeframe for care being provided by [family day care home] licensees during the hours of 6 p.m. and 6 a.m. for parents that require care and supervision of their children outside of normal operating hours (e.g. night shifts, swing shifts)." The phrase "through the night" seems to indicate that overnight care must be provided for the duration of the night, rather than at any time *during* the hours of 6 p.m. and 6 a.m., as specified in the ISOR. Additionally, the ISOR does not state why care must not exceed 24 hours. As such, the language of the regulation conflicts with the Department's description of the effect of the regulation and is unclear.

Proposed subdivision (o) is also unclear because the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning. (Cal. Code Regs., tit. 1, sec. 16, subd. (a)(1).) Proposed subdivision (o) specifies that "overnight care" shall be provided to children "between the hours of 6 p.m. and 6 a.m.," but subdivision (o) concludes with the phrase, "but not to exceed 24 hours." May the family day care home provide care for 24 hours, or only for the 12 hour period between the hours of 6 p.m. and 6 a.m.? Additionally, it is unclear from the

proposed language of subdivision (o) when the 24 hour period commences. As written, the regulation text leaves the licensee with unclear instruction regarding the timing and duration of overnight care.

1.5.2 Proposed subdivision (p)(2)

Proposed subdivision (p)(2) states: "'Play Yard' means an approved framed enclosure with integrated mesh or fabric sides approved by the United States Consumer Product Safety Commission." Proposed subdivision (p)(2) is unclear because the language of the regulation conflicts with the description of the effect of the regulation in the ISOR. (Cal. Code Regs., tit. 1, sec. 16, subd. (a)(2).) Regarding this subdivision, the ISOR states: "The Department is adopting an alternative that permits the use of fixtures, furniture, and equipment that has not been recalled or banned by the Commission." This statement does not accurately describe what is accomplished with the adoption of subdivision (p)(2). Contrary to the explanation provided, proposed subdivision (p)(2) does not address recalled or banned products. This regulatory language merely acknowledges that fixtures, furniture, and equipment must be approved by the United States Consumer Product Safety Commission. If the Department intends to require that products not have been banned or recalled, the text must be revised to reflect that intent. As such, the regulation is unclear.

1.6 Section 102417 of the CCR

1.6.1 Proposed subdivision (d)(1)

Proposed subdivision (d)(1) states: "Fixtures, furniture, and equipment that have been banned or recalled by the United States Consumer Product Safety Commission shall not be used for children in care or accessible." Proposed subdivision (d)(1) is unclear because the language of the regulation conflicts with the description of the effect of the regulation in the ISOR. (Cal. Code Regs., tit. 1, sec. 16, subd. (a)(2).) Proposed subdivision (d)(1) establishes a prohibition on the use of banned or recalled products at a family day care home. Regarding this subdivision, the ISOR declares: "This section is being adopted to require licensees to only use fixtures, furniture, and equipment that have not been banned or recalled by the Commission....Banned and recalled items shall be removed from the facility unless the licensee has proof that the manufacturer has corrected the item to meet the Commission's standards." This statement does not accurately describe what is accomplished by the adoption of subdivision (d)(1). Contrary to the explanation provided, proposed subdivision (d)(1) does not require the removal of banned or recalled items from the family day care home. This regulatory language merely states that fixtures, furniture, and equipment that have been banned or recalled shall not be used for children in care or accessible. If the Department intends to require the removal of products that are banned or recalled (except when corrected), the text must be revised to reflect that intent. As such, the regulation is unclear.

Proposed subdivision (d)(1) is also unclear because the language is not "written or displayed so that the meaning of the regulations will be easily understood by those persons directly affected by them." (Gov. Code, sec. 11349, subd. (c).) As written, "accessible" is vague. Accessible to the children in care or to any other individual who may enter the family day care home? Because the term "accessible" is not easily understood by those persons directly affected, the regulation is unclear.

1.6.2 Proposed subdivision (d)(1)(A)

Proposed subdivision (d)(1)(A) states:

> If the United States Consumer Product Safety Commission authorizes a correction to a banned or recalled item, proof of the correction showing it meets the new United States Consumer Product Safety Commission standards shall be maintained at the facility and shall be available to the licensing agency for review.

Proposed subdivision (d)(1)(A) is unclear because the language of the regulation conflicts with the description of the effect of the regulation included in the ISOR. (Cal. Code Regs., tit. 1, sec. 16, subds. (a)(2).) Regarding this subdivision, the ISOR declares: "Banned and recalled items shall be removed from the [family day care home] ***unless*** the licensee has proof that the manufacturer has corrected the item to meet the Commission's standards." (Emphasis added.) This statement does not accurately describe what is accomplished by the adoption of subdivision (d)(1)(A). The qualification that a banned or recalled product need not be removed from the family day care home if the United States Consumer Product Safety Commission has authorized a correction of the product and the manufacturer has corrected the item is not specified in regulation. If the Department intends to allow for the use of a banned or recalled product or accessibility of a banned or recalled product at the family day care home, assuming the United States Consumer Product Safety Commission authorized a correction to the banned or recalled item and the problem has been corrected, the text must be revised to reflect that intent. As such, proposed subdivision (d)(1)(A) is unclear.

1.7 Section 102425 of the CCR

1.7.1 Proposed subdivision (a)

Proposed subdivision (a) is unclear because the regulation conflicts with the description of the effect of the regulation provided in the ISOR. (Cal. Code Regs., tit. 1, sec. 16, subd. (a)(2).) Proposed subdivision (a) reads: "There shall be one crib or play yard for each infant who is unable to climb out of the crib or play yard." Regarding the adoption of subdivision (a), the ISOR states:

> This section is being adopted to require licensees to use safe cribs, play yards, and to reduce the risk of suffocation, entrapment, overheating, and strangulation....
>
> American Academy of Pediatrics as well as Caring for Our Children National Recommendations and the California SIDS Program recommend a crib or play yard as the safest place for an infant to sleep as well as providing a safe sleep environment within the crib or play yard.

Proposed subdivision (a) narrows the use of cribs or play yards to infants "unable to climb out of the crib or play yard," which conflicts with the description in the ISOR. The ISOR says nothing about an infant's ability to climb out of a crib or play yard specifically, but talks extensively about safety standards, which aren't explicitly addressed in the regulation. As such, the language of the regulation conflicts with the Department's description of the effect of the regulation and is unclear.

1.7.2 Proposed subdivision (a)(7)

Proposed subdivision (a)(7) is unclear because the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning. (Cal. Code Regs., tit. 1, sec. 16, subd. (a)(1).) Proposed subdivision (a)(7) states: "Soiled bedding shall be placed in a suitable container and made inaccessible to infants until washed." As written, "suitable container" is vague. What is the standard or criteria for a "suitable container"? What must the container be suitable to accomplish? Because the term "suitable" has more than one meaning, the regulation is unclear.

1.7.3 Proposed subdivision (b)(1)(A)

For the reason stated in Item 1.4, subdivision (b)(1)(A) is unclear.

1.7.4 Proposed subdivision (d)(1)

For the reason stated in Item 1.3.1, subdivision (d)(1) is unclear.

1.7.5 Proposed subdivision (d)(2)(A)

For the reasons stated in Item 1.3.2, subdivision (d)(2)(A) is unclear.

1.8 Proposed subdivision (a)(3) of section 102426 of the CCR

Proposed subdivision (a)(3) states: "If the sleeping arrangements are not situated in such a way that the licensee can be assured of hearing a child wake up, a monitor system shall be used." Proposed subdivision (a)(3) is unclear because the phrase "monitor system" is vague. The phrase is not defined in the regulation or the governing statute, thus the phrase does not have a

meaning generally familiar to those "directly affected." (Cal. Code Regs., tit. 1, sec. 16, subd. (a)(3).) As written, it is unclear whether the Department is requiring the use of an audio monitor, video monitor, or "a home monitor that check[s] a baby's breathing and/or heart rate," as referenced in the Department of Public Health's "Safe Sleep Environments for Infants" that was identified as a document relied upon in the ISOR. Without further clarification, it is not readily apparent which type of home monitor must be used. Because "monitor system" is left undefined, the regulation is unclear.

For the reasons discussed above, the Department failed to comply with the clarity standard of the APA. The Department must make proposed modifications available to the public for comment for at least 15 days pursuant to Government Code section 11346.8, subdivision (c), and section 44 of title 1 of the CCR before resubmitting this regulatory action to OAL for review. Additionally, any comments made in relation to these proposed modifications must be summarized and responded to in the final statement of reasons (FSOR). (Gov. Code, sec. 11347.1, subd. (d).)

2. Necessity Standard

OAL must review regulations for compliance with the necessity standard of Government Code section 11349.1, subdivision (a)(1). Government Code section 11349, subdivision (a), defines "necessity" as follows:

> "Necessity" means the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record. For purposes of this standard, evidence includes, but is not limited to, facts, studies, and expert opinion.

To further explain the meaning of substantial evidence in the context of the necessity standard, subdivision (b) of section 10 of title 1 of the CCR provides:

> (b) In order to meet the "necessity" standard of Government Code section 11349.1, the record of the rulemaking proceeding shall include:
>
> (1) A statement of the specific purpose of each adoption, amendment, or repeal; and
>
> (2) information explaining why each provision of the adopted regulation is required to carry out the described purpose of the provision. Such information shall include, but is not limited to, facts, studies, or expert opinion. When the explanation is based upon policies, conclusions,

> speculation, or conjecture, the rulemaking record must include, in addition, supporting facts, studies, expert opinion, or other information. An "expert" within the meaning of this section is a person who possesses special skill or knowledge by reason of study or experience which is relevant to the regulation in question.

In order to provide the public with an opportunity to review and comment upon an agency's perceived need for a regulation, the APA requires that the agency describe the need for the regulation in the ISOR. The ISOR is the primary document in the rulemaking record that demonstrates that the adoption, amendment, or repeal satisfies the necessity standard. Specifically, Government Code section 11346.2, subdivision (b)(1), states:

> (b) An initial statement of reasons...shall include...:
>
> (1) A statement of the specific purpose of each adoption, amendment, or repeal, the problem the agency intends to address, and the rationale for the determination by the agency that each adoption, amendment, or repeal is reasonably necessary to carry out the purpose and address the problem for which it is proposed. The statement shall enumerate the benefits anticipated from the regulatory action, including the benefits or goals provided in the authorizing statute.

The ISOR must be submitted to OAL with the notice of proposed action (NOPA) and be made available to the public during the public comment period, along with all of the information upon which the proposal is based. (Gov. Code, sec. 11346.2, subd. (b); Gov. Code, sec. 11346.5, subds. (a)(16) and (b).) In this way, the public is informed of why the regulation is needed and why the particular provisions contained in the regulation were chosen to fulfill that need. This information is essential in order for the public to comment knowledgeably. The ISOR and all data and other factual information, studies, or reports upon which the agency relies in the regulatory action must also be included in the rulemaking record. (Gov. Code, sec. 11347.3, subds. (b)(2) and (7).)

The ISOR provided by the Department in this regulatory action was inadequate to demonstrate the need for a number of the proposed regulatory provisions. As a result, the Department must prepare an addendum to the ISOR that includes an explanation of why each of the regulatory provisions are necessary to carry out the purposes for which they were proposed. The Department will need to add the document to the rulemaking record and must make the document available for 15 days pursuant to Government Code section 11347.1. The following non-exclusive list of examples illustrates places where statements in the ISOR need to be supplemented in order to satisfy the necessity standard.

2.1 Section 101419.2 of the CCR

Proposed subdivision (b)(2) of section 101419.2 requires the completion of an Individual Infant Sleeping Plan for "[i]nfants 12 months of age and younger." The Department cited to "Caring for Our Children" standard 3.1.4.1 as justification for the adoption of proposed subdivision (b)(2). However, standard 3.1.4.1 refers to "infants up to twelve months of age," not "infants 12 months of age and younger." The Department failed to provide necessity in the rulemaking file to justify the divergence from standard 3.1.4.1. This was also an issue in the necessity statement for proposed section 102425, subdivisions (c) and (d). As such, this explanation fails to provide substantial evidence to support the need for proposed subdivision (b)(2).

2.2 Section 101429 of the CCR

Proposed subdivision (a)(2)(B) of section 101429 requires staff to conduct physical checks of sleeping infants every 15 minutes and document the results of those checks. The ISOR is very general and fails to provide substantial evidence to support the need for many of the specific provisions in proposed subdivision (a)(2)(B). For example, the ISOR does not address why physical checks every 15 minutes are necessary. The ISOR does not explain why the Department chose a time period of 15 minutes rather than five minutes, ten minutes, or even half an hour. The documents relied upon do not support the imposition of this requirement, either. Specifically, "Caring for Our Children" standard 3.1.4.1 states: "Although some state regulations require that caregivers/teachers 'check on' sleeping infants every ten, fifteen, or thirty minutes, an infant can suffocate or die in only a few minutes." This statement appears to undermine the necessity of physical checks due to the fact that an infant may suffocate or die "in only a few minutes." If the Department intends to require physical checks every 15 minutes, the Department must explain why the 15 minute period was chosen.

Additionally, the ISOR does not explain why the "specified signs of distress" were chosen by the Department. The documents incorporated by reference list numerous signs of SIDS that were not included in the proposed regulation text. For example, "Safe Sleep Environments for Infants" by the California Department of Public Health states providers should look for whether an infant is "sweaty or their chest is hot to the touch." Another example, the American Academy of Pediatrics identifies an infant's "sweating, damp hair, flushed cheeks, heat rash, and/or rapid breathing" as warnings signs of SIDS.

Furthermore, the ISOR does not address why documentation must be maintained in the child's file and available for the Department's review or why the specific documentation requirements were deemed necessary.

The aforementioned items were also an issue in the necessity statements regarding proposed section 102425, subdivision (i).

2.3 Section 101430 of the CCR

Proposed subdivision (a)(3)(A) of section 101430 requires a licensee to place "infants aged 12 months or younger on their backs for sleeping." The ISOR does not address why the Department has deviated from the standard relied upon when Caring for Our Children Standard 3.1.4.1 refers to infants "up to twelve months of age," not "infants aged 12 months or younger." Additionally, as pointed out by several commenters, it is unclear why the *licensee* must place the infant on their back for sleeping, rather than infant care center staff.

Proposed subdivision (a)(3)(A)1. enumerates the requirements related to a written medical exemption for an infant's alternate sleep position. The ISOR does not address why the written medical exemption must be completed by a licensed physician, rather than a nurse practitioner, other health care personnel, or even the infant's authorized representative.

Proposed subdivision (a)(3)(A)2. enumerates the requirements related to an infant's change of sleeping position while in care. Nowhere does the ISOR address the notification requirement or signature by the infant's authorized representative no later than the next business day.

The aforementioned items were also an issue in the necessity statement regarding proposed section 102425, subdivision (d)(2)(A).

2.4 Section 102417 of the CCR

Proposed subdivision (d)(1) of section 102417 specifies that "[f]ixtures, furniture, and equipment that have been banned or recalled by the United States Consumer Product Safety Commission shall not be used for children in care or accessible." Proposed subdivision (d)(1)(A) further specifies that proof of correction of a banned or recalled item shall be maintained at the family day care home and available for review by the Department. The ISOR provides in part:

> This section is necessary to bring Section 102417 into compliance with Federal standards for fixtures, furniture, and equipment. In accordance with national recommendations, "Caring for Our Children" standard 6.2.1.1, attached, licensees are prohibited from using banned or recalled fixtures to protect enrolled children. Banned or recalled items shall be removed from the facility unless the licensee has proof that the manufacturer has corrected the item to meet the Commission's standards. Such standards are also necessary for licensees to implement the infant safe sleep standards proposed in this Initial Statement of Reasons.

This explanation raises several issues. First, the reference to "Caring for Our Children" standard 6.2.1.1 is incorrect and does not support the adoption of the proposed regulatory text. Standard 6.2.1.1 specifically addresses play equipment and materials, rather than fixtures, furniture, and equipment generally. "Caring for Our Children" standard 5.4.5.1 states that child care facilities

"should ensure that furniture and surfaces for sleeping are in compliance with the current U.S. Consumer Product Safety Commission (CPSC) and ASTM safety standards and have not been recalled by the manufacturer." This statement is limited to sleeping equipment and supplies and does not address fixtures, furniture, and equipment generally. Additionally, "Caring for Our Children" standard 5.4.1.1 explicitly states that facilities must ensure furniture and surfaces for sleeping have not been recalled.

Second, the rulemaking record does not contain any information to support the assertion that these proposed revisions are necessary in order to comply with federal standards for fixtures, furniture, and equipment. If this is the case, the Department must identify the applicable Federal standards in the rulemaking record.

Third, the record does not reflect why proof of correction of a banned or recalled product must be maintained at the family day care home and available to the Department for review.

As such, this explanation fails to provide substantial evidence to support the need for subdivisions (d)(1) and (d)(1)(A) in section 102417.

Also of note, the explanation provided in support of the adoption of proposed subdivision (r) of section 101239 is nearly identical to the explanation provided in support of the adoption of proposed subdivision (d)(1) of section 102417. However, the language proposed in section 101239 appears to be more stringent than the language proposed in section 102417. If this distinction is intentional, the rulemaking record must contain sufficient necessity to justify the differing requirements for child care centers and family day care homes.

2.5 Section 102426 of the CCR

Proposed section 102426 establishes requirements for providing overnight care to children. The ISOR merely summarizes the Department's proposed requirements, rather than demonstrates the need for each specific requirement. Additionally, the explanation does not address why the *licensee* must satisfy the requirements enumerated in subdivision (a) rather than the provider, which is defined in subdivision (p)(3) of section 102352 to include the licensee, assistant provider, or substitute adult.

3. Failure to Follow APA Procedures

3.1 Failure to Identify Form Incorporated by Reference

The Individual Infant Sleeping Plan [LIC 9227 (6/18)] was not properly incorporated by reference pursuant to section 20 of title 1 of the CCR. Subdivision (c) of section 20 of title 1 of the CCR provides in part:

(c) An agency may "incorporate by reference" only if the following conditions are met:

(1) The agency demonstrates in the final statement of reasons that it would be cumbersome, unduly expensive, or otherwise impractical to publish the document in the California Code of Regulations.

(2) The agency demonstrates in the final statement of reasons that the document was made available upon request directly from the agency, or was reasonably available to the affected public from a commonly known or specified source....

(3) The informative digest in the notice of proposed action clearly identifies the document to be incorporated by title and date of publication or issuance....

(4) The regulation text states that the document is incorporated by reference and identifies the document by title and date of publication or issuance....

The Notice of Proposed Action (NOPA) did not identify any documents or forms incorporated by reference in this regulatory action although proposed subdivision (b)(2) of section 101419.2 incorporates by reference the Individual Infant Sleeping Plan [LIC 9227 (6/18)]. Additionally, proposed subdivision (b)(2) of section 101419.2 does not expressly state that the Individual Infant Sleeping Plan [LIC 9227 (6/18)] is incorporated by reference. Prior to resubmitting this regulatory action to OAL, the Department must properly notice the form incorporated by reference to the public in compliance with sections 20 and 44 of title 1 of the CCR. Additionally, the regulatory text must be revised to expressly state that the form is incorporated by reference. (Cal. Code Regs., tit. 1, sec. 20, subd. (c)(4).) The Department must also revise the FSOR to include the statements required pursuant to subdivisions (c)(1) and (c)(2) of section 20 of title 1 of the CCR.

3.2 Insufficient Economic Impact Assessment

The Economic Impact Assessment (EIA) included in the rulemaking record is not sufficient because it fails to comply with all of the elements required by subdivision (b)(1)(D) of Government Code section 11346.3. The EIA includes an assessment of the benefits of the regulations to the "health and welfare of infants served in child care environments," in compliance with subdivision (b)(1)(D) of Government Code section 11346.3. However, the EIA does not contain an assessment of the benefits to health and welfare of California residents generally, worker safety, and the state's environment, which is also required by Government Code section 11346.3, subdivision (b)(1)(D). The Department must prepare an addendum to the EIA that assesses all of the required elements in Government Code section 11346.3, subdivision

(b)(1)(D). The Department must notice this document to the public and make the document available for public comment for at least 15 days before resubmitting this regulatory action to OAL. (Gov. Code, sec. 11347.1.)

3.3 Insufficient Section 44 Confirmation Statement

The confirmation statement included in the rulemaking record does not comply with section 44 of title 1 of the CCR. Subdivision (b) of section 44 of title 1 of the CCR states: "[t]he rulemaking record shall contain a statement confirming that the agency complied with the requirements of this section and stating the date upon which the notice and text were mailed and the beginning and ending dates for this public availability period." The confirmation statement included in the rulemaking record is missing the date the notice and modified regulation text were transmitted to the public. Prior to resubmitting this regulatory action to OAL, the confirmation statement must be revised to add the date the notice and modified regulatory text were transmitted to the public.

3.4 Failure to Properly Notice Documents Relied Upon

The Department did not provide proper notice of all of the documents relied upon in this regulatory action. Government Code section 11346.2, subdivision (b)(2), requires the Department to include in the ISOR "[a]n identification of each technical, theoretical, and empirical study, report, or similar document, if any, upon which the agency relies in proposing the adoption, amendment, or repeal of a regulation." In the Department's ISOR, the Department identified numerous documents relied upon in compliance with subdivision (b)(2) of section 11346.2 of the Government Code. However, the NOPA in the rulemaking record refers to a 2012 white paper that proposed eight regulatory changes supporting safe sleep for infants in child care centers and family day care homes. The NOPA further states: "CDSS utilized these recommendations...to develop new requirements and strengthen existing requirements to reduce risk of unsafe sleeping environments." If the Department relied upon the 2012 white paper during the drafting of the proposed regulatory text, it should have been included in the list of documents relied upon in the ISOR. If it is a document relied upon, the 2012 white paper must be noticed to the public and made available for public comment for at least 15 days prior to resubmitting this regulatory action to OAL. (Gov. Code, sec. 11347.1.)

Additionally, the Department included a copy of the North Carolina Infant/Toddler Safe Sleep Policy (Revised 3/3/2016) in the rulemaking record. This document was never identified as a document relied upon or made available to the public for review and comment. If the Department intends to retain this document in the rulemaking record, this document must be noticed to the public as a document relied upon and made available for public comment for at least 15 days prior to resubmitting this regulatory action to OAL. (Gov. Code, sec. 11347.1.)

3.5 Failure to Include all Required Documents in the Rulemaking Record

The Department did not include all required documents in the rulemaking record. Government Code section 11347.3, subdivision (b)(7), requires the rulemaking record to include: "All data and other factual information, technical, theoretical, and empirical studies or reports, if any, on which the agency is relying in the adoption, amendment, or repeal of a regulation...." As described above, the NOPA refers to a 2012 white paper that was utilized "to develop new requirements and strengthen existing requirements to reduce risk of unsafe sleeping environments." In addition to not being identified as a document relied upon, this document was not included in the rulemaking record. (Gov. Code, sec. 11347.3, subd. (b)(7).)

Additionally, two of the documents relied upon that were identified in the ISOR are missing from the rulemaking record. These documents include: 1) American Academy of Pediatrics (healthychildren.org), "Reduce the Risk of SIDS and Suffocation" and 2) Center for Disease Control (cdc.gov/sids/Parents-Caregivers.htm), "Parents and Caregivers: Creating a Safe Sleep Area for Babies." These documents must be included in the rulemaking record prior to resubmitting this regulatory action to OAL. (Gov. Code, sec. 11347.3, subd. (b)(7).)

3.6 Failure to Properly Complete the Form 399

The information included in the Form 399 is inconsistent with the findings included in the NOPA, ISOR, and FSOR. The NOPA included in the rulemaking record states:

> These regulations do impose a mandate upon local agencies, but not on school districts. There are no "state-mandated local costs" in these regulations which require state reimbursement under Section 17500 et seq. of the Government Code (GC) because any costs associated with the implementation of these regulations are costs mandated by the federal government within the meaning of Section 17513 of the GC.

This assertion is reiterated on page 29 of the ISOR and pages 9 and 10 the FSOR. However, under the "Fiscal Effect on Local Government" section of the Form 399, the Department checked box A.5, which states: "No fiscal impact exists. This regulation does not affect any local entity or program." Additionally, under the "Fiscal Effect on Federal Funding of State Programs" section of the Form 399, the Department checked box C.3, which states: "No fiscal impact exists. This regulation does not affect any federally funded State agency or program." There is an inconsistency between the information provided in the NOPA, ISOR, and FSOR, and boxes A.5 and C.3 of the Fiscal Impact Statement. The Department must resolve these inconsistencies pursuant to direction by the Department of Finance prior to resubmitting this regulatory action to OAL.

3.7 Failure to Include All Required Information in the Updated Informative Digest

The Department did not include all of the required information in the updated informative digest (UID). Government Code section 11346.9, subdivision (b), and Government Code section 11347.3, subdivision (b)(2), require the inclusion of an UID in the rulemaking record. Specifically, subdivision (b) of Government Code section 11346.9 requires the Department to submit to OAL "a clear and concise summary of the immediately preceding laws or regulations...relating directly to the adopted, amended, or repealed regulation and the effect of the adopted, amended, or repealed regulation." Following publication of the NOPA and the 45-day public comment period, the Department conducted a 15-day public comment period to notice several substantive revisions to the regulation text. Despite the substantive revisions to the regulation text, the UID provides: "There have been no changes in applicable laws or to the effect of the proposed regulations from the laws and effects described in the Notice of Proposed Action." This statement is not accurate and does not address the change in effect of the proposed regulatory text as a result of the substantive changes. The Department must revise the UID to summarize the substantive revisions to the regulatory text. (Gov. Code, sec. 11346.9, subd. (b).)

3.8 Failure to Summarize and Respond to Public Comments

The Department did not adequately summarize and respond to all of the public comments as required by Government Code section 11346.9, subdivision (a)(3). Subdivision (a)(3) of Government Code section 11346.9 requires:

> A summary of ***each*** objection or recommendation made regarding the specific adoption, amendment, or repeal proposed, together with an explanation of how the proposed action has been changed to accommodate ***each*** objection or recommendation, or the reasons for making no change. This requirement applies only to objections or recommendations specifically directed at the agency's proposed action or to the procedures followed by the agency in proposing or adopting the action.... [Emphasis added.]

There are numerous comments that were not summarized or responded to in the FSOR. Specifically, it does not appear that a majority of the oral comments received at the public hearing on September 19, 2018 were summarized or responded to in the FSOR. Additionally, there are several Department responses that do not adequately respond to commenter concerns or that inaccurately describe the changes made to the regulations.

For example, Kari Roberts submitted an oral comment at the public hearing, which was neither summarized nor responded to in the FSOR. Ms. Roberts raised several concerns regarding this regulatory action, including concerns regarding the prohibition on swaddling, disruption of child sleep patterns, and the Department's inadequate evaluation of this action's impact on business

and continued availability of infant care in California. All of these comments were timely and applicable to the regulatory action and procedures followed by the Department. The Department did not adequately summarize or respond to Ms. Roberts' comment.

Another example, Nora Winge submitted a written comment during the 45-day public comment period. In her comment, Ms. Winge requested that the Department revise the language of section 102425 to refer to a "licensee or a qualified assistant." The Department's response states: "Though you can use an Assistant Provider to uphold the regulations to care for the children, ultimately, it is the licensee's responsibility to ensure compliance with all applicable laws and regulations." This response does not align with the proposed regulatory text. As written, only a *licensee* is allowed to physically check on an infant every 15 minutes. There is no provision in the regulatory text that allows the licensee to delegate to an assistant provider the ability to physically check on an infant every 15 minutes. As such, the Department has not adequately responded to Ms. Winge's comment.

Another example, Linda Kaercher submitted a written comment during the 15-day public comment period. In her comment, Ms. Kaercher asserted that the proposed changes to section 101429 "mak[e] infant care unaffordable, this [sic] creating a lack of supply of affordable infant care for parents who must have care in order to work." Additionally, Ms. Kaercher states: "Because infants sleep on demand...requiring a person to be in that space means that agencies must hire an additional person just to supervise sleeping infants." In response, the Department indicated that the proposed regulations were revised "to allow for the use of transparent walls or half walls allowing for constant visual and auditory supervision." This response does not address Ms. Kaercher's assertion regarding the adverse economic impact of the proposed regulations. Additionally, the Department neglects to mention in its response that the regulations were also revised to include the following language in subdivision (a)(2)(D) of section 101429: "If any infants are sleeping in a separate room from where staff are located, staff must be present in the designated sleeping room." This proposed revision is directly related to Ms. Kaercher's assertion that the proposed regulations will make infant care unaffordable and the regulation is inconsistent with the Department's response. As such, the Department has not adequately responded to Ms. Kaercher's comment.

All of the timely received, relevant comments received by the Department following publication of the NOPA must be adequately summarized and responded to in the FSOR.

3.9 Failure to Address Proposed Alternatives

The FSOR is missing a discussion regarding the alternatives considered in connection with this regulatory action. Government Code section 11346.9, subdivision (a), requires the Department to prepare a FSOR that includes, among other items:

(4) A determination with supporting information that no alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law....

(5) An explanation setting forth the reasons for rejecting any proposed alternatives that would lessen the adverse economic impact on small businesses....

In the FSOR, the Department states: "No alternatives have been presented for consideration, as the Department feels there are no safer or equivalent alternatives it is willing to consider." This statement does not satisfy the requirements enumerated in subdivision (a)(4). Additionally, this statement does not accurately describe the presentation of alternatives and the rejection of alternatives as discussed in subdivision (a)(5). Commenters submitted numerous alternatives to the proposed regulations, which were rejected by the Department. The Department must revise the FSOR to comply with the requirements enumerated in subdivisions (a)(4) and (a)(5) of Government Code section 11346.9.

4. Miscellaneous

OAL also notes the following items that must be addressed prior to the resubmittal of this regulatory action:

4.1 The proposed regulatory text contains a number of grammatical, punctuation, numbering, and underline and strikeout illustration errors. For example, in section 101429, proposed subdivision (a)(2)(B)4. is missing the proper punctuation. Another example, in section 101439.1, the Department failed to underline all of the proposed regulatory text.

4.2 OAL also notes that the proposed regulatory text contains repeated reference to the "licensing agency." However, the Department's definition of "licensing agency" included in section 101152, subdivision (l)(3), states: "See 'Department' as specified in Section 101152(d)(2). The term 'Department' supersedes the term 'Licensing Agency' as used in previous regulations." A similar definition is also found in subdivision (d)(2) of section 102352, which pertains specifically to family day care homes. As such, the Department must revise the regulatory text to refer to the "Department," rather than the "licensing agency."

CONCLUSION

For the reasons set forth above, OAL disapproved this regulatory action. Pursuant to subdivision (a) of Government Code section 11349.4, the Department may resubmit this regulatory action to OAL within 120 days of its receipt of this Decision of Disapproval. A copy of this Decision will be emailed to the Department on the date indicated below.

The Department must make all substantive regulatory text changes, which are sufficiently related to the originally noticed text, available for public comment for at least 15 days pursuant to subdivision (c) of Government Code section 11346.8 and section 44 of title 1 of the CCR. Additionally, any supplement to the ISOR or other document the Department may create or propose to add to the rulemaking record in order to address the necessity issues discussed above must be made available for public comment for at least 15 days pursuant to Government Code section 11347.1. The Department must resolve all other issues raised in this Decision of Disapproval prior to the resubmittal of this regulatory action.

If you have any questions, please contact me at (916) 323-6820.

Date: August 21, 2019

Lindsey S. McNeill
Attorney

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Director

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