

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Caring for Our Children Basics; Comment Request

AGENCY: Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: As authorized by the 2014 Omnibus Act, ACF is requesting public comment on a voluntary set of minimum health and safety standards for early care and education settings titled, "Caring for Our Children Basics."

DATES: The deadline for receipt of comments is midnight, February 17, 2015.

ADDRESSES: Submit comments to cfocbasics@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: High quality early care and education settings can have significant developmental benefits and other positive long term effects for children well into their adult years. At the same time, poor quality can result in unsafe environments that disregard children's basic physical and emotional needs leading to neglect, toxic stress, injury, or even death. It is not surprising that health and safety have been identified in multiple parent surveys as the most important factors to consider when evaluating child care options. For example, Shlay¹ found that, regardless of race/ethnicity, parents consistently prioritized health and safety over other quality features when selecting an early care arrangement.

From 2009 to 2011, 27 states made changes to licensing regulations for center-based care, and more than half made changes to licensing requirements for family child care homes. With respect to health and safety, the largest increase was in the number of states that have requirements regarding safe sleep practices (Office of Child Care's National Center on Child Care Quality Improvement & National Association for Regulatory Administration, 2013). A number of states have taken action to strengthen health and safety requirements and their enforcement in reaction to tragedies where children have been injured or died in child care (e.g., Lexie's Law (Kansas, 2010) and Joshua's List (Oklahoma, 2010)).

However, more work must be done to ensure children can learn, play, and grow in settings that are safe and secure.

Health and safety standards provide the foundation on which states and communities build a solid system of early care and education. Yet, states vary widely in the number and content of health and safety standards as well as how they monitor compliance with these standards. Some early care providers may receive no monitoring while others receive multiple visits. In addition, some early care and education providers who receive funding from multiple sources may receive repeated monitoring visits using conflicting standards. These sources can include Head Start, the Child Care and Development Fund, and the Child and Adult Care Food Program.

In testimony before the United States House Committee on Education and the Workforce, the Government Accountability Office (GAO) called attention to the multiple agencies that administer the federal investment in early learning and child care through multiple programs that sometimes have similar goals and are targeted to similar groups of children. They added that the existence of multiple programs can increase administrative costs associated with meeting varying requirements. We acknowledge that there are differences in health and safety requirements by funding stream (e.g., Head Start, Child Care Development Fund, pre-Kindergarten) and early childhood program type (e.g., center-based, home-based). While standards may vary depending on the length of the day and setting, there are some standards that must be in place to protect children no matter what type of variation in program.

The proposed model standards are called "Caring for our Children Basics." They represent the minimum standards experts believe must be in place wherever children are regularly cared for in non-parental care settings. "Caring for our Children Basics" is the first attempt to reduce the conflicts and redundancy found in standards that are used to monitor early care and education settings. These are minimum standards and should not be construed to represent all standards that would need to be present to achieve the highest quality of care and early learning. For example, the caregiver training requirements outlined in these standards are designed only to prevent harm to children, not to ensure their optimal development and learning.

This call for public comment is to obtain information to help HHS as we further develop the voluntary set of

minimum health and safety standards for early care and education settings. Because quality care cannot be achieved without consistent, basic health and safety practices in place, ACF seeks to provide a helpful reference for states and other entities as they work to improve their health and safety standards across program type. Our hope is that a voluntary common framework will assist child care licensing agencies in working towards and achieving a more consistent foundation for quality across the country upon which families can rely. In addition, ACF plans to use "Caring for Our Children Basics" in aligning health and safety efforts in early care and education at the federal level. Public input will be helpful in providing HHS with practical guidance to aid in the refinement and application of "Caring for Our Children Basics."

"Caring for Our Children Basics" is based on "Caring for Our Children: National Health and Safety Performance Standards; Guidelines for Early Care and Education Programs, Third Edition." We would like to acknowledge the extensive work of the American Academy of Pediatrics, the American Public Health Association, the National Resource Center for Health and Safety in Child Care and Early Education, and the Maternal and Child Health Bureau, Department of Health and Human Services in developing these standards.

Caring for Our Children Basics

Staffing

1.2.0.2 Background Screening

Directors of early care and education centers and caregivers/teachers in large and small family child care homes should conduct a complete background screening before employing any staff member (in addition to any individuals residing in a family child care home over age 18). Consent to the background investigation should be required for employment consideration. The comprehensive background screening should include:

- (a) The use of fingerprints for state checks of criminal history records;
- (b) The use of fingerprints for checks of Federal Bureau of Investigation criminal history records;
- (c) Clearance through the child abuse and neglect registry (if available); and
- (d) Clearance through sex offender registries (if available).

1.4.1.1/1.4.2.3 Pre-service Training/Orientation

Before or during the first 3 months of employment, training and orientation should detail health and safety issues

¹ Shlay, A. (2010). African American, White and Hispanic child care preferences: A factorial survey analysis of welfare leavers by race and ethnicity. *Social Science Research*, 39(1), 125-141.

for early care and education settings including, but not limited to, typical and atypical child development; first aid and CPR; safe sleep practices, including risk reduction of Sudden Infant Death Syndrome/Sudden Unexplained Infant Death (SIDS/SUID); infectious disease prevention; emergency preparedness; nutrition and age-appropriate feeding; medication administration; and care plan implementation for children with special health care needs. All directors or program administrators and caregivers/teachers should document receipt of training.

1.4.3.1 First Aid and CPR Training for Staff

All staff members involved in providing direct care to children should have up-to-date documentation of satisfactory completion of training in pediatric first aid and CPR skills as defined by the American Red Cross and American Heart Association. At least one staff person who has successfully completed this training should be in attendance at all times. Records of successful completion of training in pediatric first aid and CPR should be maintained in the personnel files of the facility.

1.4.5.2 Child Abuse and Neglect Education

Caregivers/teachers should be educated on child abuse and neglect prevention to establish child abuse and neglect prevention and recognition measures for the children, caregivers/teachers, and parents/guardians. The education should address physical, sexual, and psychological or emotional abuse and neglect. Caregivers/teachers are mandatory reporters of child abuse or neglect. Caregivers/teachers should be trained in compliance with their state's child abuse reporting laws.

Program Activities for Healthy Development

2.1.1.4 Monitoring Children's Development/Obtaining Consent for Screening

Programs should have a system in place for developmental and behavioral screening of all children at the beginning of a child's placement in the program, at least yearly thereafter, and as developmental concerns become apparent to staff and/or parents/guardians. This process should include parental/guardian consent and participation as well as connection to resources and support, if needed.

2.1.2.1/2.1.3.1 Personal Caregiver/Teacher Relationships for Birth to Five-Year-Olds

Programs should practice relationship-based philosophies that promote consistency and continuity of care, especially for infants and toddlers. Early care and education programs should provide opportunities for each child to build emotionally secure relationships with a limited number of caregivers/teachers. Children with special health care needs may require additional specialists to promote health and safety and to support learning.

2.2.0.1 Methods of Supervision of Children

Caregivers/teachers should directly supervise infants, toddlers, and preschoolers by sight and hearing at all times, even when the children are going to sleep, napping, or sleeping; are beginning to wake up; or are indoors or outdoors. Developmentally appropriate child-to-staff ratios should be met during all hours of operation, and safety precautions for specific areas and equipment should be followed.

2.2.0.4 Supervision near Bodies of Water

Constant supervision should be maintained when any child is in or around water. During any swimming/wading activities where either an infant or a toddler is present, the ratio should always be one adult to one infant/toddler. Caregivers/teachers should ensure that all pools meet the Virginia Graeme Baker Pool and Spa Safety Act.

2.2.0.9 Prohibited Caregiver/Teacher Behaviors

The following behaviors should be prohibited in all early care and education settings:

- (a) Use of corporal punishment;
- (b) Isolating a child where a child cannot be supervised;
- (c) Binding or tying to restrict movement or taping the mouth;
- (d) Using or withholding food as a punishment or reward;
- (e) Toilet learning/training methods that punish, demean, or humiliate a child;
- (f) Any form of emotional abuse, including rejecting, terrorizing, extended ignoring, or corrupting a child;
- (g) Any physical abuse or maltreatment of a child;
- (h) Abusive, profane, sarcastic language or verbal abuse, threats, or derogatory remarks about the child or child's family;
- (i) Any form of public or private humiliation; and

(j) Exclusion of physical activity/outdoor time as punishment.

Health Promotion and Protection

3.1.3.1 Active Opportunities for Physical Activity

Programs should demonstrate a commitment to active play for children, including infants and toddlers, indoors and outdoors every day.

3.1.4.1 Safe Sleep Practices and SIDS Risk Reduction

All staff, parents/guardians, volunteers, and others who care for infants in the early care and education setting should follow safe sleep practices as recommended by the Centers for Disease Control and Prevention (CDC) and the National Institute of Child Health and Human Development (NICHD). Cribs must be in compliance with current U.S. Consumer Product Safety Commission (CPSC) and ASTM International safety standards.

3.1.5.1 Routine Oral Hygiene Activities

Caregivers/teachers should promote the habit of regular tooth brushing. All children with teeth should brush or have their teeth brushed at least once during the hours the child is in an early care and education program.

3.2.1.4 Diaper Changing Procedure

The following diaper changing procedure should be posted in the changing area and followed to protect the health and safety of children and staff:

- Step 1: Before bringing the child to the diaper changing area, perform hand hygiene and bring supplies to the diaper changing area.
- Step 2: Carry the child to the changing table, keeping soiled clothing away from you and any surfaces you cannot easily clean and sanitize after the change. Always keep a hand on the child.
- Step 3: Clean the child's diaper area.
- Step 4: Remove the soiled diaper and clothing without contaminating any surface not already in contact with stool or urine.
- Step 5: Put on a clean diaper and dress the child.
- Step 6: Wash the child's hands and return the child to a supervised area.
- Step 7: Clean and disinfect the diaper-changing surface. Dispose of the disposable paper liner used on the diaper changing surface in a plastic-lined, hands-free, covered can. If clothing was soiled, securely tie the plastic bag used to store the clothing and send home.

Step 8: Perform hand hygiene and record the diaper change, diaper contents, and/or any problems.

Caregivers/teachers should never leave a child unattended on a table or countertop. A safety strap or harness should not be used on the diaper changing table.

3.2.2.1 Situations that Require Hand Hygiene

All staff, volunteers, and children should abide by the following procedures for hand washing, as defined by the CDC:

A. Upon arrival for the day, after breaks, or when moving from one group to another;

B. Before and after:

- Preparing food or beverages;
- Eating, handling food, or feeding a child;
- Giving medication or applying a medical ointment or cream in which a break in the skin (*e.g.*, sores, cuts, or scrapes) may be encountered;
- Playing in water (including swimming) that is used by more than one person;
- Diapering.

C. After:

- Using the toilet or helping a child use a toilet;
- Handling bodily fluid (mucus, blood, vomit);
- Handling animals or cleaning up animal waste;
- Playing in sand, on wooden play sets, and outdoors;
- Cleaning or handling the garbage.

Situations or times that children and staff should perform hand hygiene should be posted in all food preparation, hand hygiene, diapering, and toileting areas.

3.2.3.4 Prevention of Exposure to Blood and Body Fluids

Early care and education programs should adopt the use of Standard Precautions, developed by the CDC, to handle potential exposure to blood and other potentially infectious fluids. Caregivers and teachers are required to be educated regarding Standard Precautions before beginning to work in the program and annually thereafter. Training should comply with requirements of the Occupational Safety and Health Administration.

3.3.0.1 Routine Cleaning, Sanitizing, and Disinfecting

Programs should follow a routine schedule of cleaning, sanitizing, and disinfecting. Cleaning, sanitizing, and disinfecting products should not be used in close proximity to children, and adequate ventilation should be maintained during use.

3.4.1.1 Use of Tobacco, Alcohol, and Illegal Drugs

Tobacco use, alcohol, and illegal drugs should be prohibited on the premises (both indoor and outdoor environments) and in any vehicles used by the program at all times. Caregivers and teachers should not use tobacco, alcohol, or illegal drugs off the premises during the early care and education program's paid time, including break time.

3.4.3.1 Emergency Procedures

Programs should have a procedure for responding to situations when an immediate emergency medical response is required. Child-to-staff ratio should be maintained, and staff may need to be called in to maintain the required ratio. Programs should develop contingency plans for emergencies or disaster situations when it may not be possible to follow standard emergency procedures. All staff should be trained to manage an emergency until emergency medical care becomes available.

3.4.4.1 Recognizing and Reporting Suspected Child Abuse, Neglect, and Exploitation

Because caregivers/teachers are mandated reporters of child abuse and neglect, each program should have a written policy for reporting child abuse and neglect. The program should report to the child abuse reporting hotline, the Department of Social Services, child protective services, or the police as required by state and local laws, in any instance where there is reasonable cause to believe that child abuse and neglect has occurred.

3.4.4.3 Preventing and Identifying Shaken Baby Syndrome/Abusive Head Trauma

All programs should have a policy and procedure to identify and prevent shaken baby syndrome/abusive head trauma. All caregivers/teachers who are in direct contact with children, including substitute caregivers/teachers and volunteers, should receive training on preventing shaken baby syndrome/abusive head trauma; recognition of potential signs and symptoms of shaken baby syndrome/abusive head trauma; strategies for coping with a crying, fussing, or distraught child; and the development and vulnerabilities of the brain in infancy and early childhood.

3.4.5.1 Sun Safety Including Sunscreen

Caregivers/teachers should ensure sun safety for themselves and children under their supervision by keeping

infants younger than 6 months out of direct sunlight, limiting sun exposure when UV rays are strongest, wearing shatter resistant sunglasses with UV protection and hats, and applying sunscreen. Written permission from the parent/guardian for use of sunscreen should be required, and manufacturer instructions should be followed.

3.4.6.1 Strangulation Hazards

Strings and cords on toys and window coverings long enough to encircle a child's neck should not be accessible to children in early care and education programs.

3.5.0.1 Care Plan for Children with Special Health Care Needs

Children with special health care needs are defined as

. . . those who have or are at increased risk for a chronic physical, developmental, behavioral, or emotional condition and who also require health and related services of a type or amount beyond that required by children generally.²

Any child who meets these criteria in an early care and education setting should have an up-to-date Routine and Emergent Care Plan, completed by their primary care provider with input from parents/guardians, included in their on-site health record. The child care health consultant should be involved to ensure adequate information, training, and monitoring is available for early care and education staff.

3.6.1.1 Inclusion/Exclusion/Dismissal of Children

Staff should notify the parent/guardian when children develop new signs or symptoms of illness. Parent/guardian notification should be immediate for emergency or urgent issues. Staff should notify parents/guardians of children who have symptoms that require exclusion, and parents/guardians should remove children from the early care and education setting as soon as possible. For children whose symptoms do not require exclusion, verbal or written notification to the parent/guardian at the end of the day is acceptable. Most conditions that require exclusion do not require a primary care provider visit before re-entering care.

When a child becomes ill but does not require immediate medical help, a determination should be made regarding whether the child should be sent home. The caregiver/teacher should determine if the illness:

² McPherson M., Arango P., Fox H., Lauver C., McManus M., Newacheck P., . . . Strickland B. (1998). A new definition of children with special health care needs. *Pediatrics*, 102(1), 137-140.

(a) Prevents the child from participating comfortably in activities;

(b) Results in a need for care that is greater than the staff can provide without compromising the health and safety of other children;

(c) Poses a risk of spread of harmful diseases to others;

(d) Causes a fever (temperature above 101 °F [38.3 °C] orally, or 100 °F [37.8 °C] or higher taken axillary [armpit]) and behavior change or other signs and symptoms (e.g., sore throat, rash, vomiting, diarrhea). An unexplained temperature above 100 °F (37.8 °C) (armpit) in a child younger than 6 months should be medically evaluated. Any infant younger than 2 months of age with fever should get urgent medical attention.

If any of the above criteria are met, the child should be removed from direct contact with other children and monitored and supervised by a staff member known to the child until dismissed to the care of a parent/guardian or primary care provider. The local or state health department will be able to provide specific guidelines for exclusion.

3.6.1.4 Infectious Disease Outbreak Control

During the course of an identified outbreak of any reportable illness at the program, a child or staff member should be excluded if the health department official or primary care provider suspects that the child or staff member is contributing to transmission of the illness, is not adequately immunized when there is an outbreak of a vaccine-preventable disease, or the circulating pathogen poses an increased risk to the individual. The child or staff member should be readmitted when the official or primary care provider who made the initial determination decides that the risk of transmission is no longer present.

3.6.3.1/3.6.3.2 Medication Administration and Storage

The administration of medicines at the facility should be limited to:

(a) Prescription or non-prescription medication (over-the-counter) ordered by the prescribing health professional for a specific child with written permission of the parent/guardian. Written orders from the prescribing health professional should specify medical need, medication, dosage, and length of time to give medication;

(b) Labeled medications brought to the early care and education facility by the parent/guardian in the original container (with a label that includes the child's name; date filled; prescribing clinician's name; pharmacy name and

phone number; dosage/instructions; relevant warnings as well as specific, legible instructions for administration; storage; and disposal).

Programs should never administer a medication that is prescribed for one child to another child. Documentation that the medicine/agent is administered to the child as prescribed is required. Medication should not be used beyond the date of expiration. Unused medications should be returned to the parent/guardian for disposal.

All medications, refrigerated or unrefrigerated, should:

- (a) Have child-resistant caps;
- (b) Be kept in an organized fashion;
- (c) Be stored away from food;
- (d) Be stored at the proper

temperature;

(e) Be completely inaccessible to children.

3.6.3.3 Training of Caregivers/Teachers to Administer Medication

Any caregiver/teacher who administers medication should complete a standardized training course that includes skill and competency assessment in medication administration. The trainer in medication administration should be a licensed health professional. The course should be repeated according to state and/or local regulation. At a minimum, skill and competency should be monitored annually or whenever an administration error occurs.

Nutrition and Food Service

4.2.0.3 Use of U.S. Department of Agriculture (USDA), Child and Adult Care Food Program (CACFP) Guidelines

All meals and snacks and their preparation, service, and storage should meet the requirements for meals of the child care component of the USDA, CACFP, and 7 CFR 226.20.

4.2.0.6 Availability of Drinking Water

Clean, sanitary drinking water should be readily available in indoor and outdoor areas, throughout the day.

4.2.0.10 Care for Children with Food Allergies

Each child with a food allergy should have a care plan prepared for the facility by the child's primary care provider and parents/guardians, to include:

(a) Written instructions regarding the food(s) to which the child is allergic and steps to be taken to avoid that food;

(b) A detailed treatment plan to be implemented in the event of an allergic reaction, including the names, doses, and methods of prompt administration of any medications. The plan should include specific symptoms that would

indicate the need to administer one or more medications.

Based on the child's care plan, the child's caregivers/teachers should receive training for, demonstrate competence in, and implement measures for:

(a) Preventing exposure to the specific food(s) to which the child is allergic;

(b) Recognizing the symptoms of an allergic reaction;

(c) Treating allergic reactions.

The written child care plan, a mobile phone, and the proper medications for appropriate treatment if the child develops an acute allergic reaction should be routinely carried on field trips or transport out of the early care and education setting.

The program should notify the parents/guardians immediately of any suspected allergic reactions, as well as the ingestion of or contact with the problem food even if a reaction did not occur. The program should contact the emergency medical services system immediately whenever epinephrine has been administered.

Individual child's food allergies should be posted prominently in the classroom and/or wherever food is served.

4.3.1.3 Preparing, Feeding, and Storing Human Milk

Programs should develop and follow procedures for the preparation and storage of expressed human milk that ensures the health and safety of all infants, as outlined by the CDC, and prohibits the use of infant formula for a breastfed infant without parental consent. The bottle or container should be properly labeled with the infant's full name and date.

4.3.1.5 Preparing, Feeding, and Storing Infant Formula

Programs should develop and follow procedures for the preparation and storage of infant formula that ensures the health and safety of all infants. Formula provided by parents/guardians or programs should come in factory-sealed containers. The caregiver/teacher should always follow manufacturer's instructions for mixing and storing of any formula preparation. If instructions are not readily available, caregivers/teachers should obtain information from the World Health Organization's Safe Preparation, Storage and Handling of Powdered Infant Formula Guidelines. Bottles of prepared or ready-to-feed formula should be labeled with the child's full name and time and date of preparation.

4.3.1.9 Warming Bottles and Infant Foods

Bottles and infant foods can be served cold from the refrigerator and do not have to be warmed. If a caregiver/teacher chooses to warm them, bottles should be warmed under running, warm tap water or by placing them in container of warm water. Bottles should never be warmed in microwaves.

4.5.0.10 Foods that Are Choking Hazards

Caregivers/teachers should not offer foods that are associated with young children's choking incidents to children under 4 years of age (round, hard, small, thick and sticky, smooth, compressible or dense, or slippery). Food for infants should be cut into pieces ¼ inch or smaller, food for toddlers should be cut into pieces ½ inch or smaller to prevent choking. Children should be supervised while eating, to monitor the size of food and that they are eating appropriately.

4.8.0.1 Food Preparation Area Access

Infants and toddlers should not have access to the kitchen in early care and education programs. Access by older children to the kitchen, or areas where hot food is prepared, should be permitted only when supervised by adults who are qualified to follow sanitation and safety procedures.

4.9.0.1 Compliance with U.S. Food and Drug Administration (FDA) Food Code and State and Local Rules

The program should conform to applicable portions of the FDA Food Code and all applicable state and local food service rules and regulations for centers and family child care homes regarding safe food protection and sanitation practices. If the federal code and local regulations are in conflict, the health authority with jurisdiction should determine which requirement the facility must meet.

Facilities, Supplies, Equipment, Environmental Health

5.1.1.2 Inspection of Buildings

Existing and/or newly constructed, renovated, remodeled, or altered buildings should be inspected by a public inspector to ensure compliance with applicable building and fire codes before the building can be made accessible to children.

5.1.1.3 Compliance with Fire Prevention Code

Every 12 months, the early care and education facility should obtain written documentation to submit to the regulatory licensing authority that the

facility complies with a state-approved or nationally recognized Fire Prevention Code, such as the National Fire Protection Association (NFPA) 1: Fire Code.

5.1.1.5 Environmental Audit of Site Location³

An environmental audit should be conducted before construction of a new building; renovation or occupation of an older building; or after a natural disaster, to properly evaluate and, where necessary, remediate or avoid sites where children's health could be compromised. The environmental audit should include assessments of:

- (a) Potential air, soil, and water contamination on early care and education facility sites and outdoor play spaces;
- (b) Potential toxic or hazardous materials in building construction; and
- (c) Potential safety hazards in the community surrounding the site.

A written environmental audit report that includes any remedial action taken should be kept on file.

5.2.4.2 Safety Covers and Shock Protection Devices for Electrical Outlets

All accessible electrical outlets should be "tamper-resistant electrical outlets" that contain internal shutter mechanisms to prevent children from sticking objects into receptacles. In settings that do not have "tamper-resistant electrical outlets," outlets should have "safety covers" that are attached to the electrical outlet by a screw or other means to prevent easy removal by a child.

5.2.4.4 Location of Electrical Devices near Water

No electrical device or apparatus accessible to children should be located so it could be plugged into an electrical outlet while a person is in contact with a water source, such as a sink, tub, shower area, water table, or swimming pool.

5.2.8.1 Integrated Pest Management

Programs should adopt an integrated pest management program to ensure long-term, environmentally sound pest suppression through a range of practices including pest exclusion, sanitation and clutter control, and elimination of conditions that are conducive to pest infestations.

5.2.9.1 Use and Storage of Toxic Substances

All toxic substances should be used as recommended by the manufacturer and

stored in the original labeled containers. All toxic substances should be inaccessible to children. The telephone number for the poison center should be posted in a location where it is readily available in emergency situations.

5.2.9.5 Carbon Monoxide Detectors

Programs should meet state or local laws regarding carbon monoxide detectors, including circumstances when detectors are necessary. Detectors should be tested monthly. Batteries should be changed at least yearly. Detectors should be replaced at least every 5 years.

5.3.1.1/5.5.0.6/5.5.0.7 Safety of Equipment, Materials, and Furnishings

Equipment, materials, furnishings, and play areas should be sturdy, safe, in good repair, and meet the recommendations of the CPSC. Programs should attend to, including, but not limited to, the following safety hazards:

- (a) Openings that could entrap a child's head or limbs;
 - (b) Elevated surfaces that are inadequately guarded;
 - (c) Lack of specified surfacing and fall zones under and around climbable equipment;
 - (d) Mismatched size and design of equipment for the intended users;
 - (e) Insufficient spacing between equipment;
 - (f) Tripping hazards;
 - (g) Components that can pinch, shear, or crush body tissues;
 - (h) Equipment that is known to be of a hazardous type;
 - (i) Sharp points or corners;
 - (j) Splinters;
 - (k) Protruding nails, bolts, or other parts that could entangle clothing or snag skin;
 - (l) Loose, rusty parts;
 - (m) Hazardous small parts that may become detached during normal use or reasonably foreseeable abuse of the equipment and that present a choking, aspiration, or ingestion hazard to a child;
 - (n) Strangulation hazards (*e.g.*, straps, strings, etc.);
 - (o) Flaking paint;
 - (p) Paint that contains lead or other hazardous materials; and
 - (q) Tip-over hazards, such as chests, bookshelves, and televisions.
- Plastic bags, matches, candles, and lighters should not be accessible to children.

5.4.5.2 Cribs

Before purchase and use, cribs must be in compliance with current CPSC and ASTM International safety

³ Family Child Care is exempt.

standards that include ASTM F1169–10a Standard Consumer Safety Specification for Full-Size Baby Cribs, F406–10b Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards, or the CPSC 16 CFR 1219, 1220, and 1500—Safety Standards for Full-Size Baby Cribs and Non-Full-Size Baby Cribs; Final Rule.

As soon as a child can stand up, the mattress should be adjusted to its lowest position. When an infant is able to reach crib latches or potentially climb out of a crib, they should be transitioned to a different sleeping environment (such as a cot or sleeping mat). Children should never be kept in their crib by placing, tying, or wedging various fabrics, mesh, or other strong coverings over the top of the crib.

Cribs intended for evacuation purpose should be designed for carrying up to five non-ambulatory children less than 2 years of age to a designated evacuation area in the event of fire or other emergency.

Staff should only use cribs for sleep purposes and should ensure that each crib is a safe sleep environment as defined by the CDC and the NICHD. No child of any age should be placed in a crib for a time-out or for disciplinary reasons. Cribs should be placed away from window blinds or draperies.

5.5.0.8 Firearms

Early care and education programs should not have firearms, pellet or BB guns, darts, cap pistols, stun guns, paint ball guns, or objects manufactured for play as toy guns on the premises at any time. If present in a family child care home, parents should be notified and these items should be unloaded, equipped with child protective devices, and kept under lock and key with the ammunition locked separately in areas inaccessible to the children. Parents/guardians should be informed about this policy.

Play Areas/Playgrounds and Transportation

6.1.0.6/6.1.0.8/6.3.1.1 Location of Play Areas near Bodies of Water/ Enclosures for Outdoor Play Areas/Enclosure of Bodies of Water

The outdoor play area should be enclosed with a fence or natural barriers. Fences and barriers should not prevent the observation of children by caregivers/teachers. If a fence is used, it should conform to applicable local building codes in height and construction. Fence posts should be outside the fence where allowed by local building codes. These areas should

have at least two exits, with at least one being remote from the buildings.

Outside play areas should be free from bodies of water. If present, all water hazards should be enclosed with a fence that is 4 to 6 feet high or higher and comes within 3½ inches of the ground. Gates should be equipped with self-closing and positive self-latching closure mechanisms that are high enough or of a type such that children cannot open it. The openings in the fence and gates should be no larger than 3½ inches. The fence and gates should be constructed to discourage climbing. Play areas should be secured against inappropriate use when the facility is closed.

6.2.3.1 Prohibited Surfaces for Placing Climbing Equipment

Equipment used for climbing should not be placed over, or immediately next to, hard surfaces such as asphalt, concrete, dirt, grass, or flooring covered by carpet or gym mats not intended for use as surfacing for climbing equipment.

All pieces of playground equipment should be placed over a shock-absorbing material that is either the unitary or the loose-fill type, as defined by the CPSC guidelines and ASTM International Standards ASTM F1292–13 and ASTM F2223–10, extending at least 6 feet beyond the perimeter of the stationary equipment. Organic materials that support colonization of molds and bacteria should not be used. This standard applies whether the equipment is installed outdoors or indoors.

6.2.5.1 Inspection of Indoor and Outdoor Play Areas and Equipment

The indoor and outdoor play areas and equipment should be inspected daily for basic health and safety, including, but not limited to:

- (a) Missing or broken parts;
- (b) Protrusion of nuts and bolts;
- (c) Rust and chipping or peeling paint;
- (d) Sharp edges, splinters, and rough surfaces;
- (e) Stability of handholds;
- (f) Visible cracks;
- (g) Stability of non-anchored large play equipment (e.g., playhouses);
- (h) Wear and deterioration.

Observations should be documented and filed, and the problems corrected before the playground is used by children.

6.3.2.1 Lifesaving Equipment

Each swimming pool more than 6 feet in width, length, or diameter should be provided with a ring buoy and rope, a rescue tube, or a throwing line and a shepherd's hook that will not conduct

electricity. This equipment should be long enough to reach the center of the pool from the edge of the pool, should be kept in good repair, and should be stored safely and conveniently for immediate access. Caregivers/teachers should be trained on the proper use of this equipment. Children should be familiarized with the use of the equipment based on their developmental level.

6.3.5.2 Water in Containers

Bathtubs, buckets, diaper pails, and other open containers of water should be emptied immediately after use.

6.5.1.2 Qualifications for Drivers

In addition to meeting the general staff background check standards, any driver or transportation staff member who transports children for any purpose should be at least 21 years of age and have:

- (a) A valid driver's license that authorizes the driver to operate the type of vehicle being driven;
- (b) A safe driving record for more than 5 years, with no crashes where a citation was issued, as evidenced by the state Department of Motor Vehicles records;
- (c) No tobacco, alcohol, or drug use before or while driving;
- (d) No medical condition that would compromise driving, supervision, or evacuation capability;
- (e) Valid pediatric CPR and first aid certificate if transporting children alone.

The driver's license number and date of expiration, vehicle insurance information, and verification of current state vehicle inspection should be on file in the facility.

6.5.2.2 Child Passenger Safety

When children are driven in a motor vehicle other than a bus, all children should be transported only if they are restrained in a developmentally appropriate car safety seat, booster seat, seat belt, or harness that is suited to the child's weight, age, and/or psychological development in accordance with state and federal laws and regulations. The child should be securely fastened, according to the manufacturer's instructions. The child passenger restraint system should meet the federal motor vehicle safety standards contained in 49 CFR 571.213 and carry notice of compliance. Child passenger restraint systems should be installed and used in accordance with the manufacturer's instructions and should be secured in back seats only.

Car safety seats should be replaced if they have been recalled, are past the manufacturer's "date of use" expiration date, or have been involved in a crash

that meets the U.S. Department of Transportation crash severity criteria or the manufacturer's criteria for replacement of seats after a crash.

6.5.2.4 Interior Temperature of Vehicles

The interior of vehicles used to transport children for field trips and out-of-program activities should be maintained at a temperature comfortable to children. All vehicles should be locked when not in use, head counts of children should be taken after transporting to prevent a child from being left unintentionally in a vehicle, and children should never be intentionally left in a vehicle unattended.

6.5.3.1 Passenger Vans⁴

Early care and education programs that provide transportation for any purpose to children, parents/guardians, staff, and others should not use 15-passenger vans whenever possible. Caregivers/teachers should be knowledgeable about the laws of the state(s) in which their vehicles, including passenger vans, will be registered and used.

Infectious Disease

7.2.0.1 Immunization Documentation

Programs should require that all parents/guardians of enrolled children provide written documentation of receipt of immunizations appropriate for each child's age. Infants, children, and adolescents should be immunized as specified in the "Recommended Immunization Schedules for Persons Aged 0 Through 18 Years," developed by the Advisory Committee on Immunization Practices of the CDC, the American Academy of Pediatrics, and the American Academy of Family Physicians. Children whose immunizations are not up-to-date or have not been administered according to the recommended schedule should receive the required immunizations, unless contraindicated or for legal exemptions.

7.2.0.2 Unimmunized Children

If immunizations have not been or are not to be administered because of a medical condition, a statement from the child's primary care provider documenting the reason why the child is temporarily or permanently medically exempt from the immunization requirements should be on file. If immunizations are not to be administered because of the parents'/guardians' religious or philosophical

beliefs, a legal exemption with notarization, waiver, or other state-specific required documentation signed by the parent/guardian should be on file. The parent/guardian of a child who has not received the age-appropriate immunizations prior to enrollment and who does not have documented medical, religious, or philosophical exemptions from routine childhood immunizations should provide documentation of a scheduled appointment or arrangement to receive immunizations. An immunization plan and catch-up immunizations should be initiated upon enrollment and completed as soon as possible.

If a vaccine-preventable disease to which children are susceptible occurs in the facility and potentially exposes the unimmunized children who are susceptible to that disease, the health department should be consulted to determine whether these children should be excluded for the duration of possible exposure or until the appropriate immunizations have been completed. The local or state health department will be able to provide guidelines for exclusion requirements.

7.2.0.3 Immunization of Caregivers/Teachers

Caregivers/teachers should be current with all immunizations routinely recommended for adults by the Advisory Committee on Immunization Practices of the CDC as shown in the "Recommended Adult Immunization Schedule" in the following categories:

(a) Vaccines recommended for all adults who meet the age requirements and who lack evidence of immunity (*i.e.*, lack documentation of vaccination or have no evidence of prior infection); and

(b) Recommended if a specific risk factor is present.

If a staff member is not appropriately immunized for medical, religious, or philosophical reasons, the early care and education facility should require written documentation of the reason.

If a vaccine-preventable disease to which adults are susceptible occurs in the facility and potentially exposes the unimmunized adults who are susceptible to that disease, the health department should be consulted to determine whether these adults should be excluded for the duration of possible exposure or until the appropriate immunizations have been completed. The local or state health department will be able to provide guidelines for exclusion requirements.

Policies

9.2.4.1 Written Plan and Training for Handling Urgent Medical Care or Threatening Incidents

The program should have a written plan for reporting and managing any incident or unusual occurrence that is threatening to the health, safety, or welfare of the children, staff, or volunteers. Staff training procedures should also be included. The management, documentation, and reporting of the following types of incidents should be addressed:

- (a) Lost or missing child;
- (b) Suspected maltreatment of a child (also see state's mandates for reporting);
- (c) Suspected sexual, physical, or emotional abuse of staff, volunteers, or family members occurring while they are on the premises of the program;
- (d) Injuries to children requiring medical or dental care;
- (e) Illness or injuries requiring hospitalization or emergency treatment;
- (f) Mental health emergencies;
- (g) Health and safety emergencies involving parents/guardians and visitors to the program;
- (h) Death of a child or staff member, including a death that was the result of serious illness or injury that occurred on the premises of the early care and education program, even if the death occurred outside of early care and education hours;
- (i) The presence of a threatening individual who attempts or succeeds in gaining entrance to the facility.

9.2.4.3 Disaster Planning, Training and Communication

Early care and education programs should consider how to prepare for and respond to emergency or natural disaster situations that may require evacuation, lock-down, or shelter-in-place and have written plans, accordingly. The following topics should be addressed, including, but not limited to, regularly scheduled practice drills, procedures for notifying and updating parents, and the use of the daily class roster(s) to check attendance of children and staff during an evacuation or drill when gathered in a safe space after exit and upon return to the program.

9.2.4.7 Sign-In/Sign-Out System

Programs should have a sign-in/sign-out system to track those who enter and exit the facility. The system should include name, contact number, relationship to facility (*e.g.*, parent/guardian, vendor, guest, etc.), and recorded time in and out.

⁴Family Child Care is exempt.

9.2.4.8 Authorized Persons To Pick Up Child

Children may only be released to adults authorized by parents or legal guardians and whose identity has been verified by photo identification. Names, addresses, and telephone numbers of persons authorized to take a child under care out of the facility should be obtained during the enrollment process and regularly reviewed, along with clarification/documentation of any custody issues/court orders. The legal guardian(s) of the child should be established and documented at this time.

9.4.1.12 Record of Valid License, Certificate, or Registration of Facility

Every facility should hold a valid license, certificate, or documentation of registration prior to operation as required by the local and/or state statute.

9.4.2.1 Contents of Child Records

Programs should maintain a confidential file for each child in one central location on-site and should be immediately available to the child's caregivers/teachers (who should have parental/guardian consent for access to records), the child's parents/guardians, and the licensing authority upon request. The file for each child should include the following:

- (a) Pre-admission enrollment information;
- (b) Admission agreement signed by the parent/guardian at enrollment;
- (c) Initial and updated health care assessments, completed and signed by the child's primary care provider, based on the child's most recent well care visit;
- (d) Health history completed by the parent/guardian at admission;
- (e) Medication record;
- (f) Authorization form for emergency medical care;
- (g) Written informed consent forms signed by the parent/guardian allowing the facility to share the child's health records with other service providers.

10.4.2.1 Frequency of Inspections for Child Care Centers, Large Family Child Care Homes, and Small Family Child Care Homes

The licensing inspector or monitoring staff should make an onsite inspection to measure compliance with licensing/regulatory rules prior to issuing an initial license and at least two inspections each year to each center and large and small family child care home thereafter. At least one of the inspections should be unannounced, and more if they are needed for the

facility to achieve satisfactory compliance or if the facility is closed at any time. Sufficient numbers of licensing inspectors should be hired to provide adequate time visiting and inspecting programs to ensure compliance with regulations.

The number of inspections should not include those inspections conducted for the purpose of investigating complaints. Complaints should be investigated promptly, based on severity of the complaint. States are encouraged to post the results of licensing inspections, including complaints, on the Internet for parent and public review. Parents/guardians should be provided easy access to the licensing rules and made aware of how to report complaints to the licensing agency.

Dated: December 12, 2014.

Linda K. Smith,

Deputy Assistant Secretary for Early Childhood Development, Administration for Children and Families, U.S. Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0996]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 20, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0389. Also

include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review—(OMB Control Number 0910-0389)—Extension

Section 112(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 506 (21 U.S.C. 356). The section authorizes FDA to take appropriate action to facilitate the development and expedite the review of new drugs, including biological products, intended to treat a serious or life-threatening condition and that demonstrate a potential to address an unmet medical need. Under section 112(b) of FDAMA, FDA issued guidance to industry on fast track policies and procedures outlined in section 506 of the FD&C Act. The guidance discusses collections of information that are specified under section 506 of the FD&C Act, other sections of the Public Health Service Act (the PHS Act), or implementing regulations. The guidance describes three general areas involving the collection of information: (1) Fast track designation requests, (2) premeeting packages, and (3) requests to submit portions of an application. Of these, fast track designation requests and premeeting packages, in support of receiving a fast track program benefit, provide for additional collections of information not covered elsewhere in statute or regulation. Information in support of fast track designation or fast track program benefits that has previously been submitted to the Agency, may, in some cases, be incorporated into the request by referring to the information rather than resubmitting it.

Under section 506(a)(1) of the FD&C Act, an applicant who seeks fast track designation is required to submit a request to the Agency showing that the drug product: (1) Is intended for a serious or life-threatening condition and (2) has the potential to address an