## §303.10 Developmental delay.

As used in this part, “developmental delay,” when used with respect to an individual residing in a State, has the meaning given to that term under §303.300.

### §303.10 Developmental delay.

Developmental delay, when used with respect to a child residing in a State, has the meaning given that term by the State under §303.111.

### §303.10 Developmental delay.

Developmental delay, when used with respect to a child residing in a State, has the meaning given that term by the State under §303.111.

### Developmental delay (§303.10)

**Comment:** A few commenters suggested amending the definition of developmental delay. One commenter recommended that the definition be revised to specifically reference infants and toddlers with mild disabilities. Another commenter recommended that the regulations clarify that any definition of developmental delay that the State adopts in response to public comments should not exclude from eligibility children who are eligible under the State’s pre-existing definition of developmental delay.

**Discussion:** These comments are addressed in our discussion of the comments on §303.111.

**Changes:** None.

### §303.16 Infants and toddlers with disabilities.

(a) As used in this part, infants and toddlers with disabilities means individuals from birth through age two who need early intervention services because they—

1. Are experiencing developmental delays, as measured by appropriate diagnostic instruments and procedures, in one or more of the following areas:
   - Cognitive development.
   - Physical development, including vision and hearing.
   - Communication development.
   - Social or emotional development.
   - Adaptive development; or

2. Have a diagnosed physical or mental condition that has a high probability of resulting in developmental delay.

(b) The term may also include, at a State’s discretion, children from birth through age two years old who need early intervention services because the child—

1. Is experiencing a developmental delay, as measured by appropriate diagnostic instruments and procedures, in one or more of the following areas:
   - Cognitive development.
   - Physical development, including vision and hearing.
   - Communication development.
   - Social or emotional development.
   - Adaptive development; or

2. Has a diagnosed physical or mental condition that—
   - Has a high probability of resulting in developmental delay; and
   - Includes conditions such as chromosomal abnormalities; genetic or congenital disorders; severe sensory impairments; inborn errors of metabolism; disorders reflecting disturbance of...
who are at risk of having substantial developmental delays if early intervention services are not provided.

NOTE 1: The phrase “a diagnosed physical or mental condition that has a high probability of resulting in developmental delay,” as used in paragraph (a)(2) of this section, applies to a condition if it typically results in developmental delay. Examples of these conditions include chromosomal abnormalities; genetic or congenital disorders; severe sensory impairments, including hearing and vision; inborn errors of metabolism; disorders reflecting disturbance of the development of the nervous system; congenital infections; disorders secondary to exposure to toxic substances, including fetal alcohol syndrome; and severe attachment disorders.

NOTE 2: With respect to paragraph (b) of this section, children who are at risk may be eligible under this part if a State elects to extend services to that population, even though they have not been identified as disabled. Under this provision, States have the authority to define who would be “at risk of having substantial developmental delays if early intervention services are not provided.” In defining the “at risk” population, States may include well-known biological and environmental factors that can be identified and that place infants and toddlers “at risk” for developmental delay. Commonly cited factors include low birth weight, respiratory

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<td>who are at risk of having substantial developmental delays if early intervention services are not provided.</td>
<td>disturbance of the development of the nervous system; congenital infections; and disorders secondary to exposure to toxic substances, including fetal alcohol syndrome.</td>
<td>the development of the nervous system; congenital infections; severe attachment disorders; and disorders secondary to exposure to toxic substances, including fetal alcohol syndrome.</td>
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<td>(b) Infant or toddler with a disability also may include, at a State's discretion, an at-risk infant or toddler (as defined in §303.5).</td>
<td>(b) Infant or toddler with a disability may include, at a State's discretion, an at-risk infant or toddler (as defined in §303.5).</td>
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<td>(c) Infant or toddler with a disability also may include, at a State’s discretion, a child with a disability who is eligible for services under section 619 of the Act and who previously received services under this part until the child enters, or is eligible under State law to enter, kindergarten or elementary school, as appropriate, provided that any programs under this part serving the child must include--(1) An educational component that promotes school readiness and incorporates pre-literacy, language, and numeracy skills; and (2) A written notification to parents of their rights and responsibilities in determining whether their child will continue to receive services under this part or participate in preschool programs under section 619 of the Act.</td>
<td>(c) Infant or toddler with a disability may include, at a State’s discretion, a child with a disability who is eligible for services under section 619 of the Act and who previously received services under this part until the child enters, or is eligible under State law to enter, kindergarten or elementary school, as appropriate, provided that any programs under this part must include--(1) An educational component that promotes school readiness and incorporates pre-literacy, language, and numeracy skills for children ages three and older who receive Part C services pursuant to §303.211; and (2) A written notification to parents of a child with a disability who is eligible for services under section 619 of the Act and who previously received services under this part of their rights and responsibilities in determining whether their child will continue to receive services under this part or participate in preschool programs under section 619 of the Act.</td>
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Former Regulations

Evaluation and Assessment and Eligibility Regulations

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<td>distress as a newborn, lack of oxygen, brain hemorrhage, infection, nutritional deprivation, and a history of abuse or neglect. It should be noted that “at risk” factors do not predict the presence of a barrier to development, but they may indicate children who are at higher risk of developmental delay than children without these problems.</td>
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Infant or toddler with a disability (§303.21)

Comment: Several commenters supported our proposed definition of infant or toddler with a disability.

Commenters specifically supported the definition in §303.21(a)(2) regarding eligibility for children with conditions that have a high probability of resulting in a child’s developmental delay. One commenter supported the inclusion of “chromosomal abnormalities” in the examples of conditions in §303.21(a)(2)(ii) that have a high probability of resulting in a child’s developmental delay. A few commenters requested clarification of the list of examples of these conditions in §303.21(a)(2)(ii). One commenter requested that “severe attachment disorders” be added as an example in §303.21(a)(2)(ii). Another commenter requested that the qualifier “severe” be deleted from the reference to “sensory impairments” in §303.21(a)(2)(ii) because mild hearing losses can result in developmental delays. One commenter suggested that we clarify that the definition of infant or toddler with a disability in §303.21(a)(2) does not require that the infant or toddler with a disability have a severe or chronic condition and that the definition includes at-risk infants and toddlers.

Another commenter requested that we revise §303.21 to provide that a State’s definition of infant or toddler with a disability can include, at the State’s discretion, children with disabilities who are eligible for services under section 619 of the Act and previously were served under Part C of the Act until such children enter, or are eligible to enter, kindergarten. Another commenter was concerned that services will be denied to children transitioning between Part C of the Act and Part B of the Act during the summer months despite the requirements in §303.21(c) and the definition of child in §303.6.

Discussion: The examples of diagnosed conditions that have a high probability of resulting in developmental delay listed in §303.21(a)(2)(ii) were taken from Note 1 following current §303.16, which states: The phrase ‘a diagnosed physical or mental condition that has a high probability of resulting in developmental delay,’ … applies to a condition if it typically results in developmental delay. Examples of these conditions include chromosomal abnormalities; genetic or congenital disorders; severe sensory impairments, including hearing and vision; inborn errors of metabolism; disorders reflecting disturbance of the development of the nervous system; congenital infections; disorders secondary to exposure to toxic substances, including fetal alcohol syndrome; and severe attachment disorders.

The reference to “severe attachment disorders,” which was included in Note 1, was inadvertently omitted from proposed §303.21(a)(2)(ii) and we have added it to §303.21(a)(2)(ii) as an example of a diagnosed condition that has a high probability of resulting in developmental delay.

Concerning the commenter’s request that the qualifier “severe” be deleted from the phrase “sensory impairments,” in §303.21(a)(2)(ii), we agree with the commenter that even a mild sensory impairment may result in developmental delay and have revised the definition accordingly.
Concerning the commenter’s request that we clarify that the definition of infant or toddler with a disability does not require that the infant or toddler with a disability have a severe or chronic condition, §303.21 includes various groups of children such as an infant or toddler who is experiencing a developmental delay, or who has a diagnosed physical or mental condition that has a high probability of resulting in developmental delay and in no way limits eligibility to infants or toddlers with severe or chronic conditions. Thus, the clarification recommended by the commenter is not necessary.

With respect to the commenter’s request that the definition of infant or toddler with a disability in §303.21 include at-risk infants and toddlers, §303.21(b) provides that the definition of infant or toddler with a disability may include, at a State’s discretion, an at-risk infant or toddler, as defined in §303.5. It is the Department’s position that each State must be provided discretion to develop a definition of infant or toddler with a disability that meets the unique needs of its population. The definition of infant or toddler with a disability addresses sufficiently and appropriately the issue of at-risk infants and toddlers and, therefore, we have not revised the definition as requested.

Concerning the request to revise the definition of infant or toddler with a disability to include children who are eligible for services under section 619 of the Act and were previously served under Part 303, §303.21(c) already makes clear that the definition of infant or toddler with a disability may include, at a State’s discretion, a child with a disability who is eligible for services under section 619 of the Act and who previously received services under Part 303 until the child enters, or is eligible under State law to enter, kindergarten or elementary school.

Summer services should not be denied to a child transitioning from early intervention services under Part C of the Act to programs under Part B of the Act simply because that child transitions during the summer months. Once a child is determined eligible for Part B services, an IEP, or if consistent with 34 CFR 300.323(b) of the Part B regulations, an IFSP, must be developed. If a child’s IEP Team determines that extended school year services are necessary for the child to receive FAPE, the child must receive those services in accordance with the IEP (or IFSP under 34 CFR 300.323(b) of the Part B regulations). Issues relating to transition of infants and toddlers from Part C to Part B services are discussed in more detail in the Analysis of Comments and Changes for subpart C in response to comments received on §303.209.

Changes: We have revised §303.21(a)(2)(ii) to add “severe attachment disorders” to the list of diagnosed conditions that have a high probability of resulting in developmental delay. Additionally, we have removed the word “severe” as a qualifier to the term “sensory impairments” in §303.21(a)(2)(ii).

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<td>§ 303.161 State definition of developmental delay. Each application must include the State’s definition of “developmental delay,” as described in § 303.300.</td>
<td>§303.111 State definition of developmental delay. Each system must include the State’s rigorous definition of developmental delay, consistent with §§303.10 and 303.203(c), that will be used by the State in carrying out programs under Part C of the Act in order to appropriately identify infants and toddlers with disabilities who are in need of services under §303.111 State definition of developmental delay. Each system must include the State's rigorous definition of developmental delay, consistent with §§303.10 and 303.203(c), that will be used by the State in carrying out programs under Part C of the Act in order to appropriately identify infants and toddlers with disabilities who are in need of services under</td>
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Part C of the Act. The definition must--
(a) Describe, for each of the areas listed in §303.18(a)(1), the evaluation and assessment procedures, consistent with §303.320, that will be used to measure a child's development; and

(b) Specify the level of developmental delay in functioning or other comparable criteria that constitute a developmental delay in one or more of the developmental areas identified in §303.21(a)(1).

State definition of developmental delay (§303.111)
Comment: Some commenters strongly supported the flexibility afforded States through the regulatory language in §303.111, regarding a State’s definition of developmental delay. Other commenters requested that the Department define the term “rigorous” in §303.111. One commenter requested that the regulations clarify that a “rigorous” definition of developmental delay does not necessarily mean that States must change their definitions to make them more rigorous than they were before the enactment of the 2004 amendments to the Act. The same commenter expressed concern that any definition of developmental delay under §303.111 would exclude certain children who are eligible under the State’s existing definition of developmental delay.

Another commenter suggested that §303.111 be amended to include “children” with delays, and not only “infants and toddlers,” because of a State’s option to make Part C services available to children ages three and older pursuant to §303.211.

Discussion: The definition of developmental delay in §303.111, which is aligned with section 635(a)(1) of the Act, replaces the definition of developmental delay in current §§303.161 and 303.300. Consistent with §303.203(c), a State’s definition of developmental delay is considered to be rigorous under Part C of the Act if the definition meets the requirements in §303.111(a) and (b), and, was established in accordance with the public participation requirements in new §303.208(b).

As required in §303.111, a State’s definition of developmental delay must include: (1) consistent with §303.321, a description of the evaluation and assessment procedures that will be used to measure a child’s development; and (2) a description of the specific level of developmental delay in functioning or other comparable criteria that constitute a developmental delay in one or more of the developmental areas identified in §303.21(a)(1). Additionally, in order to be “rigorous”, each State’s definition of developmental delay must be established in accordance with the public participation requirements in new §303.208(b) to enable parents, EIS providers, Council members and other stakeholders and members of the public to comment on the State’s definition. Section 303.111 does not require a State to revise, or preclude a State from using, its existing definition of developmental delay as long as the definition meets the requirements in §303.111 and was established in accordance with the public participation requirements that are set forth in new §303.208(b) after December 2004.
### Evaluation, Assessment, and Nondiscriminatory Procedures

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We decline to replace the phrase “infants and toddlers,” as used in §303.111, with the term “child,” as one commenter requested, because this change is unnecessary. The definition of “infant or toddler with a disability” in §303.211 includes any child to whom the State elects to offer Part C services under section 635(c) of the Act and §303.211.

**Changes:** None.

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<td>Each application must include information to demonstrate that the requirements in §§ 303.322 and 303.323 are met.</td>
<td>(a) Subject to paragraph (b) of this section, each system must ensure the performance of-(1) A timely, comprehensive, multidisciplinary evaluation of the functioning of each infant or toddler with a disability in the State; and (2) A family-directed identification of the needs of the family of the infant or toddler, to assist appropriately in the development of the infant or toddler.</td>
<td>(a) Subject to paragraph (b) of this section, each system must ensure the performance of-(1) A timely, comprehensive, multidisciplinary evaluation of the functioning of each infant or toddler with a disability in the State; and (2) A family-directed identification of the needs of the family of the infant or toddler, to assist appropriately in the development of the infant or toddler.</td>
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<td>(b) The evaluation and family-directed identification required in paragraph (a) of this section must meet the requirements of §303.320.</td>
<td>(b) The evaluation and family-directed identification required in paragraph (a) of this section must meet the requirements of §303.321.</td>
<td>(b) The evaluation and family-directed identification required in paragraph (a) of this section must meet the requirements of §303.321.</td>
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**Comment:** Two commenters recommended adding the word “voluntary” before “family-directed identification of the needs of the family” in paragraph (a)(2) of this section to clarify that the Part C program is voluntary and that the assessment cannot take place unless and until parents agree to the assessment.

**Discussion:** We agree that the family-directed identification of the needs of the family referenced in §303.113(a)(2) is voluntary on the part of the family. However, it is not necessary to revise §303.113 because, in §303.113(b), we make clear that the family assessment must meet the requirements in §303.321. Section 303.321(c)(2), in turn, provides that the family assessment must be voluntary on the part of the family. We decline to make the requested change because it would be redundant to repeat the family assessment requirements in §303.113.

**Changes:** None.

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<th>§303.300 State eligibility criteria and procedures.</th>
<th>Incorporated into the following regulations:</th>
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<td>Each statewide system of early intervention services must include the eligibility criteria and procedures, consistent with § 303.16, that</td>
<td>§303.111 State definition of developmental delay</td>
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<td>§303.203 Statewide system and</td>
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Former Regulations will be used by the State in carrying out programs under this part. (a) The State shall define *developmental delay* by—
(1) Describing, for each of the areas listed in § 303.16(a)(1), the procedures, including the use of informed clinical opinion, that will be used to measure a child’s development; and
(2) Stating the levels of functioning or other criteria that constitute a developmental delay in each of those areas.

(b) The State shall describe the criteria and procedures, including the use of informed clinical opinion, that will be used to determine the existence of a condition that has a high probability of resulting in developmental delay under § 303.16(a)(2).

(c) If the State elects to include in its system children who are at risk under § 303.16(b), the State shall describe the criteria and procedures, including the use of informed clinical opinion, that will be used to identify those children.

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| will be used by the State in carrying out programs under this part. (a) The State shall define *developmental delay* by—
(1) Describing, for each of the areas listed in § 303.16(a)(1), the procedures, including the use of informed clinical opinion, that will be used to measure a child’s development; and
(2) Stating the levels of functioning or other criteria that constitute a developmental delay in each of those areas. (b) The State shall describe the criteria and procedures, including the use of informed clinical opinion, that will be used to determine the existence of a condition that has a high probability of resulting in developmental delay under § 303.16(a)(2). (c) If the State elects to include in its system children who are at risk under § 303.16(b), the State shall describe the criteria and procedures, including the use of informed clinical opinion, that will be used to identify those children. | $\text{§303.203 Statewide system and description of services.}$  Each application must include --
(c) The State’s rigorous definition of developmental delay as required under §§303.10 and 303.111. | $\text{§303.203 Statewide system and description of services.}$  Each application must include --
(c) The State’s rigorous definition of developmental delay as required under §§303.10 and 303.111. |

$\text{§303.204 Application’s definition of at-risk infants and toddlers and description of services.}$  
If the State provides services under this part to...
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<td>at-risk infants and toddlers through the statewide system, the application must include- (a) The State’s definition of at-risk infants and toddlers with disabilities who are eligible in the State for services under Part C of the Act (consistent with §§303.5 and 303.21(b)); and (b) A description of the early intervention services provided under this part to at-risk infants and toddlers with disabilities who meet the State’s definition described in paragraph (a) of this section.</td>
<td>at-risk infants and toddlers through the statewide system, the application must include- (a) The State’s definition of at-risk infants and toddlers with disabilities who are eligible in the State for services under Part C of the Act (consistent with §§303.5 and 303.21(b)); and (b) A description of the early intervention services provided under this part to at-risk infants and toddlers with disabilities who meet the State’s definition described in paragraph (a) of this section.</td>
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**Application’s definition of at-risk infants and toddlers and description of services (§303.204)**

**Comment:** One commenter supported the requirements of this section and the definition of the term at-risk infant or toddler in §303.5, but expressed concern that serving at-risk infants and toddlers would be an additional fiscal burden on States.

**Discussion:** Serving at-risk infants or toddlers is a State option under section 632(5)(B)(i) of the Act. Section 303.204 incorporates the requirement from section 637(a)(4) of the Act that the State describe the services to be provided to at-risk infants and toddlers through the Part C statewide system only if the State chooses to make “at-risk infants and toddlers” eligible for Part C services in the State.

If a State elects to provide services to at-risk infants and toddlers with disabilities, the State must include the definition of at-risk infants and toddlers with disabilities in its application. A State also must include in its application a description of the early intervention services to be provided to at-risk infants and toddlers with disabilities. Section 303.204 does not require a State to provide services to at-risk infants and toddlers; therefore, these requirements and the financial responsibilities associated with their implementation are applicable only to those States that choose to include “at-risk infants and toddlers” in their definition of infant or toddler with a disability under §303.21(b).

**Changes:** None.

**Comment:** One commenter recommended adding language in §303.204(a) to encourage States to examine closely the percentage of premature infants who eventually receive Part C services and to use this information to develop presumptive eligibility criteria for at-risk infants and toddlers to receive Part C services.

**Discussion:** The Act does not require States to develop presumptive eligibility criteria for at-risk infants and toddlers. Sections 632(1), 632(5)(B)(i), and 637(a)(4) of the Act provide States with the option to make at-risk infants and toddlers eligible under Part C of the Act, and further to determine the Part C services that will be made available to these children. This flexibility enables each State to determine the eligibility criteria for at-risk infants and toddlers that are most appropriate in the State. Examining data on premature infants who eventually receive Part C services is one method a State could use to help determine its eligibility criteria for at-risk infants or toddlers, but there are other methods that might be more appropriate for other States. For example, a State with a large number of homeless infants and toddlers who have high rates of developmental delay could determine that such children should be presumptively included in its definition of at-risk infants and toddlers.
Therefore, while a State could certainly use data on premature infants who eventually receive Part C services to inform its decision on the eligibility criteria the State will use for at-risk infants or toddlers, it is not appropriate to require all States to do so.

Changes: None.

### § 303.322 Evaluation and assessment.

(a) General. (1) Each system must include the performance of a timely, comprehensive, multidisciplinary evaluation of each child, birth through age two, referred for evaluation, and a family-directed identification of the needs of each child’s family to appropriately assist in the development of the child.

(2) The lead agency shall be responsible for ensuring that the requirements of this section are implemented by all affected public agencies and service providers in the State.

(b) Definitions of evaluation and assessment.

As used in this part—

(1) **Evaluation** means the procedures used by appropriate qualified personnel to determine a child’s initial and continuing eligibility under this part, consistent with the definition of “infants and toddlers with disabilities” in §303.16, including determining the status of the child in each of the developmental areas in paragraph (c)(3)(ii) of this section.

(2) **Assessment** means the ongoing procedures used by appropriate qualified personnel throughout the period of a child’s eligibility under this part to identify—

(i) The child’s unique strengths and needs and the services appropriate to meet those needs; and

### § 303.320 Evaluation and assessment of the child and family and assessment of service needs.

(a) General. (1) Each lead agency must ensure, for each child under the age of three who is referred for evaluation or services under this part and suspected of having a disability, the performance of—

(i) A timely, comprehensive, multidisciplinary evaluation of the child;

(ii) An assessment of the child;

(iii) An assessment of the family as described in paragraph (c) of this section, if the parent and family concur; and

(iv) An assessment of service needs, as described in paragraph (d) of this section, if the child is determined to meet the definition of an infant or toddler with a disability in §303.21.

(2)(i) An evaluation is the method used to review the assessments of the child and the family to determine a child’s initial and continuing eligibility under this part, consistent with the definition of infant or toddler with a disability in §303.21.

(ii) An evaluation is the method used to review the assessments of the child and the family to determine a child’s initial and continuing eligibility under this part, consistent with the definition of infant or toddler with a disability in §303.21.

### § 303.321 Evaluation of the child and assessment of the child and family.

(a) General. (1) The lead agency must ensure that, subject to obtaining parental consent in accordance with §303.420(a)(2), each child under the age of three who is referred for evaluation or early intervention services under this part and suspected of having a disability, receives—

(i) A timely, comprehensive, multidisciplinary evaluation of the child in accordance with paragraph (b) of this section unless eligibility is established under paragraph (a)(3)(i) of this section; and

(ii) If the child is determined eligible as an infant or toddler with a disability as defined in §303.21—

(A) A multidisciplinary assessment of the unique strengths and needs of that infant or toddler and the identification of services appropriate to meet those needs;

(B) A family-directed assessment of the resources, priorities, and concerns of the family and the identification of the supports and services necessary to enhance the family’s capacity to meet the developmental needs of that infant or toddler. The assessments of the child and family are described in paragraph (c) of this section and these assessments may occur simultaneously with the evaluation,
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(ii) The resources, priorities, and concerns of the family and the supports and services necessary to enhance the family’s capacity to meet the developmental needs of their infant or toddler with a disability.

(c) Evaluation and assessment of the child. The evaluation and assessment of each child must—

1. Be conducted by personnel trained to utilize appropriate methods and procedures;
2. Be based on informed clinical opinion; and
3. Include the following:
   i. A review of pertinent records related to the child’s current health status and medical history.
   ii. An evaluation of the child’s level of functioning in each of the following developmental areas:
      A. Cognitive development.
      B. Physical development, including vision and hearing.
      C. Communication development.
      D. Social or emotional development.
      E. Adaptive development.
   iii. An assessment of the unique needs of the child in terms of each of the developmental areas in paragraph (c)(3)(ii) of this section, including the identification of services appropriate to meet those needs.

(d) Family assessment. (1) Family assessments under this part must be family-directed and designed to determine the resources, priorities, and concerns of the family and the

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- The resources, priorities, and concerns of the family and the supports and services necessary to enhance the family’s capacity to meet the developmental needs of their infant or toddler with a disability.

(c) Evaluation and assessment of the child. The evaluation and assessment of each child must—

1. Be conducted by personnel trained to utilize appropriate methods and procedures;
2. Be based on informed clinical opinion; and
3. Include the following:
   i. A review of pertinent records related to the child’s current health status and medical history.
   ii. An evaluation of the child’s level of functioning in each of the following developmental areas:
      A. Cognitive development.
      B. Physical development, including vision and hearing.
      C. Communication development.
      D. Social or emotional development.
      E. Adaptive development.
   iii. An assessment of the unique needs of the child in terms of each of the developmental areas identified in §303.21(a)(1).

(b) Procedures for assessment of the child.

1. Assessment of the child means reviewing available pertinent records that relate to the child’s current health status and medical history and conducting personal observation and assessment of the child in order to identify the child’s unique strengths and needs, including an identification of the child’s level of functioning in each of the following developmental areas: cognitive development; physical development; communication development; social or emotional development; and adaptive development based on objective criteria, which must include informed clinical opinion.

2. Qualified personnel must use their informed clinical opinion to assess a child’s present level of functioning in each of the developmental areas identified in §303.21(a)(1) and the lead agency must ensure that informed clinical opinion may be used by qualified personnel to establish a child’s

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- provided that the requirements of paragraph (b) of this section are met.

2. As used in this part--

(i) Evaluation means the procedures used by qualified personnel to determine a child’s initial and continuing eligibility under this part, consistent with the definition of infant or toddler with a disability in §303.21. An initial evaluation refers to the child’s evaluation to determine his or her initial eligibility under this part;

(ii) Assessment means the ongoing procedures used by qualified personnel to identify the child’s unique strengths and needs and the early intervention services appropriate to meet those needs throughout the period of the child’s eligibility under this part and includes the assessment of the child, consistent with paragraph (c)(1) of this section and the assessment of the child’s family, consistent with paragraph (c)(2) of this section; and

(iii) Initial assessment refers to the assessment of the child and the family assessment conducted prior to the child’s first IFSP meeting.

3. A child’s medical and other records may be used to establish eligibility (without conducting an evaluation of the child) under this part if those records indicate that the child’s level of functioning in one or more of the developmental areas identified in §303.21 constitutes a developmental delay or that the child otherwise meets the criteria for an infant or toddler with a disability under §303.21. If the child’s Part C eligibility
(c) Procedures for assessment of the family. Assessment of the family means identification of the family’s resources, priorities, and concerns, and the supports and services necessary to enhance the family’s capacity to meet the developmental needs of the family’s infant or toddler with a disability, as determined not just through the use of an assessment tool, but through a voluntary personal interview with the family.

(d) Assessment of service needs. If the child meets the definition of infant or toddler with a disability in §303.21, an assessment of the service needs of the infant or toddler with a disability and the child’s family must include a review of the evaluation (including the assessment of the child and family) and available pertinent records and conducting personal observation and assessment of the infant or toddler with a disability in order to identify the early intervention services appropriate to meet the child’s unique needs in each of the developmental areas identified in paragraph (b)(1) of this section.

(e) Timelines. (1) Except as provided in paragraph (e)(2) of this section, the evaluation and initial assessment of each child (including the family assessment) must be completed within the 45-day time period required in § 303.321(e).

(2) The lead agency shall develop procedures to ensure that in the event of exceptional circumstances that make it impossible to complete the evaluation and assessment within 45 days (e.g., if a child is ill), public agencies will—

(i) Document those circumstances; and

(ii) Develop and implement an interim IFSP, to the extent appropriate and consistent with § 303.345 (b)(1) and (b)(2).

(2) Any assessment that is conducted must be voluntary on the part of the family.

(3) If an assessment of the family is carried out, the assessment must—

(i) Be conducted by personnel trained to utilize appropriate methods and procedures;

(ii) Be based on information provided by the family through a personal interview; and

(iii) Incorporate the family’s description of its resources, priorities, and concerns related to enhancing the child’s development.

(3) If an assessment of the family is carried out, the assessment must—

(i) Be conducted by personnel trained to utilize appropriate methods and procedures;

(ii) Be based on information provided by the family through a personal interview; and

(iii) Incorporate the family’s description of its resources, priorities, and concerns related to enhancing the child’s development.

(e) Timelines. (1) Except as provided in paragraph (e)(2) of this section, the evaluation and initial assessment of each child (including the family assessment) must be conducted in accordance with paragraph (c) of this section.

(ii) Qualified personnel must use informed clinical opinion when conducting an evaluation and assessment of the child. In addition, the lead agency must ensure that informed clinical opinion may be used as an independent basis to establish a child’s eligibility under this part even when other instruments do not establish eligibility; however, in no event may informed clinical opinion be used to negate the results of evaluation instruments used to establish eligibility under paragraph (b) of this section.

(d) Assessment of service needs. If the child meets the definition of infant or toddler with a disability in §303.21, an assessment of the service needs of the infant or toddler with a disability and the child’s family must include a review of the evaluation (including the assessment of the child and family) and available pertinent records and conducting personal observation and assessment of the infant or toddler with a disability in order to identify the early intervention services appropriate to meet the child’s unique needs in each of the developmental areas identified in paragraph (b)(1) of this section.

(e) Timelines. (1) Except as provided in paragraph (e)(2) of this section, the evaluation and initial assessment of each child (including the family assessment) must be conducted in accordance with paragraph (c) of this section. (ii) Qualified personnel must use informed clinical opinion when conducting an evaluation and assessment of the child. In addition, the lead agency must ensure that informed clinical opinion may be used as an independent basis to establish a child’s eligibility under this part even when other instruments do not establish eligibility; however, in no event may informed clinical opinion be used to negate the results of evaluation instruments used to establish eligibility under paragraph (b) of this section.

(2) The lead agency shall develop procedures to ensure that in the event of exceptional circumstances that make it impossible to complete the evaluation and assessment within 45 days (e.g., if a child is ill), public agencies will—

(i) Document those circumstances; and

(ii) Develop and implement an interim IFSP, to the extent appropriate and consistent with § 303.345 (b)(1) and (b)(2).

(2) Any assessment that is conducted must be voluntary on the part of the family.

(3) If an assessment of the family is carried out, the assessment must—

(i) Be conducted by personnel trained to utilize appropriate methods and procedures;

(ii) Be based on information provided by the family through a personal interview; and

(iii) Incorporate the family’s description of its resources, priorities, and concerns related to enhancing the child’s development.

(e) Timelines. (1) Except as provided in paragraph (e)(2) of this section, the evaluation and initial assessment of each child (including the family assessment) must be conducted in accordance with paragraph (c) of this section.

(ii) Qualified personnel must use informed clinical opinion when conducting an evaluation and assessment of the child. In addition, the lead agency must ensure that informed clinical opinion may be used as an independent basis to establish a child’s eligibility under this part even when other instruments do not establish eligibility; however, in no event may informed clinical opinion be used to negate the results of evaluation instruments used to establish eligibility under paragraph (b) of this section.

(3) If an assessment of the family is carried out, the assessment must—

(i) Be conducted by personnel trained to utilize appropriate methods and procedures;

(ii) Be based on information provided by the family through a personal interview; and

(iii) Incorporate the family’s description of its resources, priorities, and concerns related to enhancing the child’s development.
of the child (including any assessments of the child and family) and assessment of service needs, as well as the initial IFSP meeting, must be completed within 45 days from the date the lead agency obtains parental consent to conduct an evaluation of the child.

(ii) Lead agencies must ensure that parental consent to conduct an evaluation under §303.420(a) is obtained as soon as possible once a child is referred for evaluation under this part.

(2) The lead agency must develop procedures to ensure that in the event of exceptional circumstances that make it impossible to complete the evaluation (including any assessments of the child and family) and assessment of service needs within 45 days (e.g., if a child is ill) from receiving parental consent, public agencies will--

(i) Document those circumstances; and

(ii) Develop and implement an interim IFSP, to the extent appropriate and consistent with §303.345.

(c) Procedures for assessment of the child and family. (1) An assessment of each infant or toddler with a disability must be conducted by qualified personnel in order to identify the child’s unique strengths and needs and the early intervention services appropriate to meet those needs. The assessment of the child must include the following--

(i) A review of the results of the evaluation conducted under paragraph (b) of this section; (ii) Personal observations of the child; and (iii) The identification of the child’s needs in each of the developmental areas in §303.21(a)(1).

(2) A family-directed assessment must be conducted by qualified personnel in order to identify the family’s resources, priorities, and concerns and the supports and services necessary to enhance the family's capacity to
Evaluation of the child and assessment of the child and family (new §303.321) (proposed §303.320)

**Comment:** Several commenters noted that there were significant changes in proposed §303.320 that did not appear to have a basis in the Act. Commenters stated that changing the definitions of evaluation and assessment procedures at this point would have major implications for State rules, policies, procedures, professional development, parent training, data systems, and State monitoring systems.

**Discussion:** The definitions of evaluation and assessment in proposed §303.320(a), (b), and (c) were not substantively different from current §303.322(b)(1) through (b)(2); instead, the changes made in proposed §303.320 were intended to clarify the current requirements. However, because of the concerns raised by some of the commenters, we have revised the definitions in new §303.321(a)(2) (proposed §303.320(a), (b), and (c)) to provide further clarification. Specifically, we have clarified that evaluation means the procedures used by qualified personnel to determine a child’s initial and continuing eligibility under this part, consistent with the definition of infant or toddler with a disability in §303.21. Also, we have clarified that assessment means the ongoing procedures used by qualified personnel to identify a child’s unique strengths and needs and the early intervention services appropriate to meet those needs throughout the period of a child’s eligibility under this part and includes the assessment of the child, consistent with new §303.321(c)(1) (proposed §303.320(b)) and the assessment of the child’s family, consistent with new §303.321(c)(2) (proposed §303.320(c)).

We have further clarified the definition of assessments in new §303.321(a)(1)(ii) to incorporate the language from section 636(a)(1) and (a)(2) of the Act, which requires each statewide system to provide for each eligible child: (1) A multidisciplinary assessment of the unique strengths and needs of the infant or toddler and the identification of services appropriate to meet those needs; and (2) A family-directed assessment of the resources, priorities, and concerns of the family and the identification of the supports and services necessary to enhance the family's capacity to meet the developmental needs of the infant or toddler.

In making these revisions to the definitions of evaluation and assessment, we determined it was also appropriate to clarify what is meant by the terms “initial evaluation” and “initial assessment.” Other sections of these regulations, particularly in the context of the 45-day timeline reflected in new §303.310 (proposed §303.320(e)), often refer to the initial evaluation and the initial assessment. For this reason, we have clarified in new §303.321(a)(1)(ii) of these regulations that the evaluations and assessments required by §303.322(a)(1) and (a)(2) of the Act must be completed within 45 days of a family’s initial request for services.
§303.321(a)(2)(i) that the term “initial evaluation” refers to the child’s evaluation to determine his or her initial eligibility under this part. We have clarified in new §303.321(a)(2)(ii) that the term “initial assessment” refers to assessments of the child and the family conducted prior to the child’s initial IFSP meeting, both of which must be conducted within the 45-day timeline described in new §303.310 (proposed §303.320(e)), even if family members other than the parent agree to participate but are unavailable to complete the family assessment. We do not believe that these definitions are new concepts under the Part C program; rather, we view them as clarifying the terminology used so that the field can more easily distinguish between evaluations and assessments that occur throughout a child’s time in the Part C program and the initial evaluation and initial assessment that must be completed, along with the initial IFSP meeting, within 45 days after the child is referred to the Part C program.

**Changes:** The definitions of evaluation and assessment in new §303.321(a)(2) (proposed §303.320(a), (b), and (c)) have been clarified to reflect the language in section 636(a)(1) and (a)(2) of the Act. We also have added definitions of the terms initial evaluation and initial assessment to this section.

**Comment:** A few commenters requested clarification on the distinction between an assessment and an evaluation, as used in new §303.321(a) (proposed §303.320(a), (b), and (c)).

**Discussion:** We agree with the commenters regarding the need for clarification and, therefore, have revised new §303.321 (proposed §303.320). An evaluation, as defined in new §303.321(a)(2)(i) (proposed §303.320(a)(2)(i)), means the procedures used by qualified personnel to determine a child’s initial and continuing eligibility under this part, and can include, pursuant to new §303.321(b) (proposed §303.320(a)(2)), activities such as administering an evaluation instrument; taking the child’s history (including interviewing the parent); identifying the child’s level of functioning in each of the developmental areas in §303.21(a)(1); gathering information from other sources such as family members, other care-givers, medical providers, social workers, and educators, if necessary, to understand the full scope of the child’s unique strengths and needs; and reviewing medical, educational, or other records.

We recognize that the three separate references to assessments in proposed §303.320(a) (assessment of the child, assessment of the family, and assessment of service needs) may have caused confusion. To facilitate understanding, we have defined the term assessment, in new §303.321(a)(2)(ii), to mean the ongoing procedures used by qualified personnel to identify the child’s unique strengths and needs and the early intervention services appropriate to meet those needs throughout the period of a child’s eligibility under this part and to include, the assessment of the child and the assessment of the child’s family.

We also have removed all general references to assessment of service needs as used in the proposed regulations. These changes are further discussed in the Analysis of Comments and Changes section addressing comments received on proposed §303.320(d).

**Changes:** We have reorganized and revised new §303.321(a) (proposed §303.320(a), (b), and (c)) to set out clear definitions of the terms evaluation and assessment.

**Comment:** One commenter requested that the final regulations clarify that the assessment in new §303.321(a)(1)(ii) (proposed §303.320(a)(1)(ii)) is a “developmental” assessment of the child.

**Discussion:** The assessment of the child includes the identification of the child’s needs in each of the developmental areas in §303.21(a)(1), the definition of an infant or toddler with a disability; however, the assessment also includes identifying the unique strengths and needs of the child and the early intervention services appropriate to meet those needs; reviewing the results of an evaluation; and conducting personal observations of...
### Former Regulations vs. Draft Regulations vs. 2011 Regulations

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<td>the child. Therefore, it is the Department’s position that limiting the assessment of the child to a developmental assessment is not appropriate.</td>
<td>Changes: None.</td>
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**Comment:** Some commenters expressed concern about the language in new §303.321(a)(1)(ii) (proposed §303.320(a)(1)(iii)), regarding the assessment of the family. One commenter stated that the requirement to conduct a family assessment before determining an infant or toddler’s eligibility presents an undue and unnecessary burden on State Part C programs. The commenter recommended that language be added to the regulations to ensure that family assessments do not have to be conducted unless an infant or toddler is determined to be eligible for early intervention services. Two commenters requested that we revise this section to clarify the assessments that must be conducted as part of an initial evaluation of a child referred under this part.

**Discussion:** An assessment of a child and family as defined in new §303.321(a)(1), (a)(2)(ii), (a)(3), (a)(4), and (c) (proposed §303.320(a)(1), (a)(2)(iii), (a)(3)(b), and (c)) is only required if the child is determined to be eligible to receive services under this part. We have added language to new §303.321(a)(1)(ii) (proposed §303.320(a)(1)(ii) and (a)(1)(iii)) to make this clear.

**Changes:** We have revised the introduction to new §303.321(a)(1)(ii) (proposed §303.320(a)(1)(ii) and (a)(1)(iii)) to read “If the child is determined eligible as an infant or toddler with a disability as defined in §303.21.”

**Comment:** Several commenters expressed concern that proposed §303.320(a)(1)(iv) may be inconsistent with section 636(a) and (d)(4) of the Act with regard to when service needs are identified. These commenters were concerned that determining service needs prior to the IFSP meeting could preempt important decisions that need to be made as part of the IFSP process. One commenter recommended that the language in current §303.322(c)(3)(iii), which requires the “assessment of the unique needs of the child… including the identification of services appropriate to meet those needs” be retained instead. Several commenters recommended that we replace the term “service needs” in proposed §303.320(a)(1)(iv) with the phrase “unique needs in each of the developmental areas,” which is used in current §303.322(c)(3)(iii). Other commenters did not support the assessment of service needs as part of the evaluation process, because this assessment typically is part of the IFSP process, completed after the IFSP Team has determined child and family outcomes.

**Discussion:** Based on commenters’ requests for clarification regarding what must be included in an assessment, we have revised new §303.321(a)(2)(ii) and (c)(1) (proposed §303.320(b), (c), and (d)) to provide that an assessment means the ongoing procedures used by qualified personnel to identify the child’s unique strengths and needs and the early intervention services appropriate to meet those needs. We also have clarified that an assessment of the child must include a review of the results of the evaluation conducted under new §303.321(b) (proposed §303.320(a)(2)), personal observations of the child, and the identification of the child’s needs in each of the developmental areas in §303.21(a)(1). Because we have revised new §303.321(a)(2)(ii) and (c)(1) (proposed §303.320(b), (c), and (d)) to state that the assessment of the child must include identification of the child’s unique strengths and needs and the early intervention services appropriate to meet those needs, we have removed the language requiring an assessment of service needs from new §303.321(a)(1) (proposed §303.320(a)(iv)) and have removed proposed §303.320(d) from the final regulations. The results of the assessment of the child, together with the results of the assessment of the family, are the basis for the IFSP Team’s determination of which early intervention services would be appropriate to meet the needs of the infant or toddler with a disability and his or her family.

Regarding commenters’ concern that using assessments to identify the early intervention services appropriate for a child prior to an IFSP meeting is inconsistent with the Act, section 636(a) of the Act, provides that a statewide system must include a multidisciplinary assessment of the unique...
strengths and needs of the infant or toddler and the identification of services appropriate to meet such needs. Section 636 of the Act states that the IFSP shall contain a statement of specific early intervention services and §§303.343 and 303.344 require the IFSP Team (which includes the parent) to identify the early intervention services appropriate to meet the child’s needs at the IFSP Team meeting. This requirement is not replaced by the assessment; rather, the assessment serves to inform the IFSP Team process by identifying the developmental strengths and needs of the child. We believe that this facilitates rather than preempts important decisions that need to be made through the IFSP process.

Changes: The procedures for assessment of the child have been changed in new §303.321(a)(1)(ii) and (c)(1) (proposed §303.320(b), (c), and (d)) to include the identification of the child’s unique strengths and needs and the early intervention services appropriate to meet those needs. Further, new §303.321(c)(1) (proposed §303.320(b), (c), and (d)) has been revised to clarify that an assessment of the child must include a review of the results of the evaluation conducted under new §303.321(b) (proposed §303.320(a)(2)), personal observations of the child, and the identification of the child’s needs in each of the developmental areas in §303.21(a)(1).

Comment: A few commenters requested that new §303.321(a)(3)(i) (proposed §303.320(a)(2)(iii)) be clarified to require that a child, prior to the IFSP meeting, receive an assessment in accordance with new §303.321(c) (proposed §303.320(b) and (c)) even when medical records and other information are adequate to determine eligibility without an evaluation in order to inform IFSP members of the child’s unique strengths and needs.

Discussion: We agree that clarification is needed because we inadvertently referred in the proposed section to “assessment” instead of “evaluation” in the parenthetical (without conducting an assessment of the child and the family).” Additionally, regardless of whether a child’s eligibility is determined through medical records or an evaluation, once a child is determined to be eligible to receive services under Part C of the Act, initial assessments of the child and family must be completed.

Activities that are the basis of the initial assessment of the child may occur with the initial evaluation of the child. We have added the phrase “if the child is determined eligible as an infant or toddler with a disability as defined in §303.21” to new §303.321(a)(1)(ii) (proposed §303.320(a)(1)(ii) and (a)(1)(iii)) to clarify that an assessment is required once a child is determined eligible, regardless of how eligibility is determined. We also have added a sentence to new §303.321(a)(3)(i) (proposed §303.320(a)(2)(iii)) to further explain that, if a child’s Part C eligibility is established through a review of his or her medical or other records, the lead agency or EIS provider must conduct assessments, including the family assessment, pursuant to new §303.321(c) (proposed §303.320).

Changes: As noted elsewhere, we have added the phrase “if the child is determined eligible as an infant or toddler with a disability as defined in §303.21” to new §303.321(a)(1)(ii) (proposed §303.320(a)(1)(ii) and (a)(1)(iii)). We also have added a sentence to new §303.321(a)(3)(i) (proposed §303.320(a)(2)(iii)) to further explain that, if a child’s Part C eligibility is established under that paragraph, the lead agency or EIS provider must conduct assessments, including the family assessment, pursuant to new §303.321(c) (proposed §303.320).

Comment: One commenter expressed concern about proposed §303.320(a)(3), which required that evaluations and assessments of the child and family be conducted in the child’s or family’s native language, as appropriate. The commenter stated that the phrase “as appropriate” weakens the requirement. Another commenter requested that the regulations restore the phrase “unless it is clearly not feasible to do so” from current §303.323(a) and, further, that these regulations use the phrase consistently when referencing native language. Two commenters requested that we add “or other mode of communication” after “native language” in proposed §303.320(a)(3) to ensure that the native language requirement is not narrowly interpreted to exclude sign language.
### Former Regulations

One commenter requested that, because of the family-centered nature of the Part C program, the assessment should be conducted in the family’s native language, regardless of whether the child has or uses a different native language.

**Discussion:** For clarity and in response to the comments about removing the phrase “as appropriate” and adding the phrases “unless clearly not feasible to do so” and “other mode of communication” to proposed §303.320(a)(3), regarding conducting evaluations and assessments of the child, we have deleted the phrase “in the child’s or family’s native language (as appropriate)” from new §303.321(a)(4) (proposed §303.320(a)(3)), and added new provisions in §§303.321(a)(5) and (a)(6).

We specify in new §303.321(a)(5) that, unless clearly not feasible to do so, all evaluations and assessments of a child must be conducted in the native language of the child, in accordance with the definition of native language in §303.25. We also specify in new §303.321(a)(6) that, unless clearly not feasible to do so, family assessments must be conducted in the native language of the family members being assessed, in accordance with the definition of native language in §303.25. The “unless clearly not feasible to do so” standard acknowledges that there may be instances when conducting evaluations or assessments in the native language of the child, parent, or family member is not possible because, for example, interpreters for a particular language cannot be located, despite best efforts. If on-site interpreters cannot be located for a particular language despite best efforts, other methods of communication in the native language, such as using telephonic interpreters, should also be explored when an interpreter is needed and appropriate, for the evaluation and assessment.

We do not agree with the commenter that evaluations and assessments of the child should only be conducted in the parent’s or family’s native language, regardless of whether the child has or uses a different language. Section 303.321(a)(5), together with §303.25(a)(2), recognize that while it sometimes may be appropriate to conduct an evaluation or assessment of an infant or toddler in the language normally used by the child’s parents, in other cases it may be determined to be developmentally appropriate to evaluate or assess the child in the language normally used by the child if that language differs from his or her parents. For example, evaluations or assessments of infants are often conducted in the native language of the parent because the parents are present and infants are pre-verbal both in their expressive and receptive language abilities. In contrast, many evaluations and assessments of toddlers (i.e., children who are between the ages of one and three) are conducted in the toddler’s native language, rather than the native language of the parent. We believe that ultimately the qualified personnel conducting the evaluation or assessment is in the best position to determine which language is developmentally appropriate—that of the child or the parent.

**Changes:** We have removed the phrase “in the child’s or family’s native language (as appropriate)” from new §303.321(a)(4) (proposed §303.320(a)(3)), and added new provisions in §§303.321(a)(5) and (a)(6). We specify in new §303.321(a)(5) that, unless clearly not feasible to do so, all evaluations and assessments of a child must be conducted in the native language of the child, in accordance with the definition of native language in §303.25.

We also specify in new §303.321(a)(6) that, unless clearly not feasible to do so, family assessments must be conducted in the native language of the family members being assessed, in accordance with the definition of native language in §303.25.

**Comment:** A few commenters recommended that subpart D include provisions that clearly specify that multidisciplinary evaluations include the participation of qualified personnel with knowledge of the disability that may be indicated, particularly given the inclusion of informed clinical opinion in new §303.321(a)(3)(ii) (proposed §303.320(b)(1) and (b)(2)). The commenters stated that for clinical opinion to be valid, personnel

### Draft Regulations

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<td><strong>Comment:</strong> A few commenters recommended that subpart D include provisions that clearly specify that multidisciplinary evaluations include the participation of qualified personnel with knowledge of the disability that may be indicated, particularly given the inclusion of informed clinical opinion in new §303.321(a)(3)(ii) (proposed §303.320(b)(1) and (b)(2)). The commenters stated that for clinical opinion to be valid, personnel</td>
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must have knowledge and experience in the disability presented by the child. For infants and toddlers with a known disability (e.g., visual impairment), the inclusion of personnel with knowledge and training in that area of disability increases the accurate interpretation of results and is consistent both with the Act and the Part B regulations.

**Discussion**: The term evaluation is defined in new §303.321(a)(2)(i) as procedures used by qualified personnel to determine a child’s initial and continuing eligibility under Part C of the Act, consistent with the definition of infant or toddler with a disability in §303.21. The definition of qualified personnel in §303.31 requires that personnel meet State-approved or State-recognized certification, licensing, registration, or other comparable requirements that apply to the area in which the individuals are conducting evaluations or assessments or providing early intervention services. We believe that new §303.321(a)(2)(i), in conjunction with the definition of qualified personnel in subpart A of these regulations, adequately address the commenters’ concerns and, therefore, repeating the definition in this section is not necessary.

Please note, regarding the commenters’ concern about clinical opinion, for an infant or toddler with a diagnosed physical or mental condition that has a high probability of resulting in a developmental delay (i.e., known disability), clinical opinion may not be necessary to determine eligibility because, under new §303.321(a)(3)(i) (proposed §303.320(a)(2)(iii)), the child’s medical or other records may be sufficient to establish eligibility. For a child without a diagnosed physical or mental condition that has a high probability of resulting in a developmental delay, clinical opinion may be used in evaluating a child to establish eligibility but it may not be used to negate eligibility established through the use of other appropriate evaluation instruments.

**Changes**: None.

**Procedures for assessment of the child and family (new §303.321(c)) (proposed §303.320(b) and (c))**

**Comment**: Two commenters recommended adding language to new §303.321(c) (proposed §303.320(b) and (c)) to require the qualified personnel who perform the assessment of a child to be from disciplines that relate to the concerns and needs for which the child was referred to Part C services.

**Discussion**: As defined in §303.321(a)(2)(ii), the term assessment means the ongoing procedures used by qualified personnel to identify the child’s unique strengths and needs and the early intervention services appropriate to meet these needs throughout the period of the child’s eligibility under this part. These qualified personnel must review the results of the evaluation conducted under new §303.321(b) (proposed §303.320(a)(2)); observe the child; and identify the child’s needs in each of the developmental areas in §303.21(a)(1). Qualified personnel, as defined in §303.31, means personnel who have met State-approved or State-recognized certification, licensing, registration, or other comparable requirements that apply to the area in which the individuals are conducting evaluations or assessments, or providing early intervention services. Given that the term assessment encompasses the assessment of the areas of concern and need for which a child was referred to Part C services, and that personnel must be qualified, under §303.31, in the areas in which they are providing an assessment, the regulations sufficiently address the commenters’ concern. For this reason, we have not made the requested change.

**Changes**: None.

**Comment**: One commenter requested clarification as to whether informed clinical opinion in new §303.321(a)(3)(ii) (proposed §303.320(b)(2)) was an objective criterion or an assessment strategy separate from other objective criteria. Some commenters suggested that a more detailed description of informed clinical opinion than the one used in new §303.321(a)(3)(ii) (proposed §303.320(b)(2)) is needed. These commenters recommended that the Department adopt the definition of informed clinical opinion used by the National Early Childhood Technical Assistance...
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Center (NECTAC). NECTAC describes informed clinical opinion as the fusion of the assessment team’s knowledge and experience with all the information collected during an assessment, including informal measures, such as interviews with parents or observation of the child, and standardized measures such as test scores. Another commenter recommended that States be allowed to define informed clinical opinion based on the definition of developmental delay for the State.

Lastly, a few commenters requested clarification of the last phrase of new §303.321(a)(3)(ii) (proposed §303.320(b)(2)), which states that informed clinical opinion may not negate the results of assessment instruments used to establish eligibility.

### Discussion

As set forth in new §303.321(a)(3)(ii), qualified personnel must use their informed clinical opinion when conducting an evaluation or an assessment of a child. The use of informed clinical opinion by qualified personnel is neither an objective criterion nor a separate assessment strategy. Rather, informed clinical opinion is the way in which qualified personnel utilize their cumulative knowledge and experience in evaluating and assessing a child and in interpreting the results of evaluation and assessment instruments.

With regard to allowing States to define informed clinical opinion based on that State’s definition of developmental delay, we note that all States must allow qualified personnel, when conducting evaluations, to use their informed clinical opinion to determine whether the child meets the State’s definition of developmental delay. Given the Department’s monitoring experience in States where qualified personnel are not permitted to use their informed clinical opinion as a separate basis to establish eligibility, we have set forth in new §303.321(a)(3)(ii) that such personnel must be able to use informed clinical opinion as an alternate basis for establishing eligibility. Permitting informed clinical opinion to serve as a separate basis to establish a child’s eligibility under Part C of the Act is important given that standardized instruments may not capture the extent of a child’s delay. The purpose of new §303.321(a)(3)(ii) is to alleviate the confusion and to expressly permit qualified personnel to use their informed clinical opinion to establish a child’s eligibility for early intervention services under Part C of the Act, even when other instruments fail to identify or confirm the level of developmental delay to establish Part C eligibility.

Finally, we agree with the commenter that clarification is needed regarding the last phrase of new §303.321(a)(3)(ii) (proposed §303.320(b)(2)), which states that informed clinical opinion may not negate the results of assessment instruments used to establish eligibility. We inadvertently referred to “assessment” instruments instead of “evaluation” instruments in proposed §303.320(b)(2)). We have corrected this in new §303.321(a)(3)(ii) to state that in no case may informed clinical opinion be used to negate the results of evaluation instruments used to establish eligibility.

### Changes

We have clarified in new §303.321(a)(3)(ii) (proposed §303.320(b)(2)) that qualified personnel must use their informed clinical opinion when conducting an evaluation or assessment of the child and replaced the phrase “assessment instruments” with the phrase “evaluation instruments.”

### Comment

One commenter recommended that it should remain a State option to determine when a low test score for a child, in a domain such as adaptive behavior, is due to cultural preferences rather than a true delay.

### Discussion

All evaluations and assessments of a child and family under new §303.321(a)(4) must be selected and administered so as not to be racially or culturally discriminatory. In conducting an evaluation and assessment, the lead agency must ensure that they are not culturally discriminatory and must permit qualified personnel to use informed clinical opinion in interpreting the results of evaluation and assessment.
### Procedures for assessment of the family (new §303.321(c)) (proposed §303.320(c))

**Comment:** A number of commenters stated that the language in proposed §303.320(c) regarding voluntary family assessments appeared to be something that is done “to” families and not “with” families. The commenters encouraged the Department to consider the term “family-directed assessment” in the regulations when referring to a family assessment in order to make it clear that the family is a primary partner in the process.

One commenter suggested that the family assessment in new §303.321(c)(2) (proposed §303.320(c)) be based on information obtained through the use of assessment tools, voluntary personal interviews, or other appropriate methods. Another commenter recommended that language be added to new §303.321(c)(2)(ii) (proposed §303.320(c)) to ensure culturally competent services, including an awareness and respect of cultural differences in family values and child rearing practices.

**Discussion:** We have restructured new §303.321(c)(2) (proposed §303.320(c)) to identify both the purpose and the requirements of the family assessment, which requirements are set forth in new §303.321(c)(2)(i) through (c)(2)(iii). We agree with commenters and have added the term “family-directed assessment” from section 636(a)(2) of the Act to new §303.321(c)(2) to ensure that the identification of a family’s resources, priorities, and concerns are family-directed.

Concerning the commenter’s request to add “other appropriate methods,” new §303.321(c)(2)(ii) (proposed §303.320(c)) requires family assessments to be based on information obtained through an assessment tool and also on information provided by the family through a personal interview. Nothing in this provision would preclude the use of additional appropriate methods provided that the family assessment includes the use of an assessment tool and personal interview pursuant to new §303.321(c)(2)(ii) (proposed §303.320(c)). We do not believe it is appropriate to require all family assessments to use “other appropriate methods.”

Concerning the comment on culturally competent services, the requirements in §303.321(c)(2) through (c)(2)(iii) ensure that each family is involved and has the opportunity to meet with a lead agency or EIS provider to identify their priorities and concerns regarding the development of the child (i.e., by participating in the assessment, by providing information in response to the assessment tool and personal interview, and by providing a description of its resources, priorities, and concerns related to enhancing the child’s development). We believe family involvement can help ensure that services that are identified in the IFSP are relevant and culturally competent.

**Changes:** We have restructured new §303.321(c)(2)(i) through (c)(2)(iii) (proposed §303.320(c)) to list the requirements of a family assessment as follows: (1) Be voluntary on the part of each family member participating in the assessment; (2) Be based on information obtained through an assessment tool and also through an interview with those family members who elect to participate in the assessment; and (3) Include the family’s description of its resources, priorities, and concerns related to enhancing the child’s development.

**Comment:** Two commenters requested that we emphasize the important role of siblings by including them in new §303.321(c)(2) (proposed §303.320(c)). Other commenters agreed and, in addition to siblings, requested that new §303.321(c)(2) (proposed §303.320(c)) include a reference to grandparents, other family members, and others who take on roles, responsibilities, or functions traditionally taken on by family members.

**Discussion:** New §303.321(c)(2) (proposed §303.320(c)) is based on section 636(a)(2) of the Act, which requires a family-directed assessment of

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<td>instruments.</td>
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<td>Changes: None.</td>
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the resources, priorities, and concerns of the family. Including a reference to siblings or other individuals who take on the roles, responsibilities, or functions traditionally performed by family members is not necessary. The term “family” is not exclusive and, therefore, this term, as it is used in new §303.321(c)(2) (proposed §303.320(c)), would cover any of the individuals mentioned by the commenters, such as siblings. Not defining this term will allow individual families to define the term in a manner that best meets the unique needs of the child involved. 

**Changes:** None.

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<td><strong>§303.322 Determination that a child is not eligible.</strong> If, based on the evaluation conducted under §303.321, the lead agency determines that a child is not eligible under this part, the lead agency must provide the parent with prior written notice required in §303.421, and include in the notice information about the parent’s right to dispute the eligibility determination through dispute resolution mechanisms under §303.430, such as requesting a due process hearing or mediation or filing a State complaint.</td>
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**Comment:** None.

**Discussion:** New §303.320(a)(2)(ii) (proposed §303.303(a)(3)) outlines the process a lead agency must follow if, through screening, the lead agency determines that a child is not suspected of having a disability under this part. The proposed regulations did not specify the procedures a lead agency must follow if it determines, through an evaluation, that a child is not a child with a disability. We have added a new §303.322 to clarify the procedures a lead agency must follow if, after an evaluation is conducted under new §303.321 (proposed §303.320), it determines that a child is not eligible for services under this part. Specifically, a lead agency must provide the parent with prior written notice required by §303.421, and include in the notice information about the parent’s right to dispute the eligibility determination through dispute resolution mechanisms, such as requesting a due process hearing or mediation or filing a State complaint. 

**Changes:** New §303.322 has been added to identify the procedures the lead agency must follow if, after conducting an evaluation, it determines that a child is not eligible for services under this part.

**§ 303.323 Nondiscriminatory procedures.** Each lead agency shall adopt nondiscriminatory evaluation and assessment procedures. The procedures must provide that public agencies responsible for the evaluation and assessment of children and

**Incorporated into 303.320(a)(3) Evaluation and assessment of the child and family and assessment of service needs.**
families under this part shall ensure, at a
minimum, that—
(a) Tests and other evaluation materials and
procedures are administered in the native
language of the parents or other mode of
communication, unless it is clearly not feasible
to do so;
(b) Any assessment and evaluation procedures
and materials that are used are selected and
administered so as not to be racially or
culturally discriminatory;
(c) No single procedure is used as the sole
criterion for determining a child’s eligibility
under this part; and
(d) Evaluations and assessments are conducted
by qualified personnel.

§ 303.345 Provision of services before
evaluation and assessment are completed.
Early intervention services for an eligible
child and the child’s family may commence
before the completion of the evaluation and
assessment in § 303.322, if the following
conditions are met:
(a) Parental consent is obtained.
(b) An interim IFSP is developed that
includes—
(1) The name of the service coordinator
who will be responsible, consistent with
§ 303.344(g), for implementation of the
interim IFSP and coordination with other
agencies and persons; and
(2) The early intervention services that have

§303.345 Provision of services before
evaluations and assessments are completed.
Early intervention services for an eligible child
and the child’s family may commence before the
completion of the evaluation (including the
assessment of the child and family) and
assessment of service needs in §303.320, if the
following conditions are met:
(a) Parental consent is obtained.
(b) An interim IFSP is developed that
includes—
(1) The name of the service coordinator who will be responsible,
consistent with §303.344(g), for
implementation of the interim IFSP and
coordination with other agencies and persons; and

§303.345 Interim IFSPs--provision of
services before evaluations and assessments
are completed.
Early intervention services for an eligible child
and the child's family may commence before the
completion of the evaluation and
assessments in §303.321, if the following
conditions are met:
(a) Parental consent is obtained.
(b) An interim IFSP is developed that
includes—
(1) The name of the service coordinator who will be responsible,
consistent with §303.344(g), for
implementing the interim IFSP and
coordinating with other agencies and persons; and
(2) The early intervention services that have
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<td>been determined to be needed immediately by the child and the child’s family.</td>
<td>(2) The early intervention services that have been determined to be needed immediately by the child and the child's family.</td>
<td>been determined to be needed immediately by the child and the child's family.</td>
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<td>(c) The evaluation and assessment are completed within the time period required in § 303.322(e).</td>
<td>(c) Evaluations and assessments are completed within the 45-day timeline in §303.320(e).</td>
<td>(c) Evaluations and assessments are completed within the 45-day timeline in §303.310.</td>
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NOTE: This section is intended to accomplish two specific purposes: (1) To facilitate the provision of services in the event that a child has obvious immediate needs that are identified, even at the time of referral (e.g., a physician recommends that a child with cerebral palsy begin receiving physical therapy as soon as possible), and (2) to ensure that the requirements for the timely evaluation and assessment are not circumvented.

Interim IFSPs--provision of services before evaluations and assessments are completed (§303.345)

Comment: None.

Discussion: To improve clarity, we have added “interim IFSPs” to the title of this section.

Changes: We have added “Interim IFSPs” to the title of §303.345.