

DEPARTMENT OF EDUCATION**34 CFR Part 300**

RIN 1820-AB64

[Docket ID ED-2011-OSERS-0012]

Assistance to States for the Education of Children With Disabilities

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary of Education (Secretary) amends regulations for Part B of the Individuals with Disabilities Education Act (IDEA or Act). These regulations govern the Assistance to States for the Education of Children with Disabilities program, including the Preschool Grants for Children with Disabilities program. These amendments revise the parental consent requirements a public agency must meet before it may access for the first time a child's or parent's public benefits or insurance (e.g., Medicaid) to pay for services required under the Act; ensure that parents of children with disabilities are specifically informed of all of their legal protections when public agencies seek to access public benefits or insurance (e.g., Medicaid) to pay for services required under the Act; and address the concerns expressed by State educational agencies (SEAs) and local educational agencies (LEAs) that requiring parental consent each time access to public benefits or insurance is sought, in addition to the parental consent required by the Family Educational Rights and Privacy Act (FERPA) and section 617(c) of the IDEA, imposes unnecessary costs and administrative burdens.

DATES: These regulations are effective on March 18, 2013.

FOR FURTHER INFORMATION CONTACT: Mary Louise Dirrigl, U.S. Department of Education, 550 12th Street SW., Potomac Center Plaza, Room 5156, Washington, DC 20202-2641. Telephone: (202) 245-7324. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), you may call the Federal Relay System (FRS) at 1-800-877-8339.

Individuals with disabilities can obtain a copy of this document in an alternative format (e.g., Braille, large print, audiotope, or compact disk) upon request to the contact person listed in the preceding paragraph.

SUPPLEMENTARY INFORMATION:

Background: Section 300.154 of current regulations, which implements section 612(a)(12) and section 612(e) of

the Act, addresses methods for ensuring services to children with disabilities, including the responsibility of non-educational public agencies to provide or pay for required special education or related services that are necessary to ensure the provision of a free appropriate public education (FAPE) to children with disabilities in the State. Specifically, § 300.154(h), which implements section 612(e) of the Act, provides that Part B of the Act does not alter requirements imposed on States by Titles XIX and XXI of the Social Security Act or other public benefits or insurance programs. Accordingly, § 300.154(a) reinforces this important principle and emphasizes each State's obligation to develop interagency agreements or other mechanisms for coordination between educational and non-educational public agencies to ensure that all services necessary to provide FAPE are provided to children with disabilities at no cost to the parent, including services such as assistive technology devices or assistive technology services, related services, supplementary aids and services, and transition services. To that end, § 300.154(a), consistent with section 612(a)(12)(A)(i) of the Act, requires States to identify the financial responsibility of non-educational public agencies, including the State Medicaid agency or other public insurers of children with disabilities, for providing services required for FAPE, and specifies that the financial responsibility of Medicaid and other public insurers of children with disabilities must precede the financial responsibility of the LEA responsible for developing the child's IEP. Further, § 300.154(b)(1)(ii), provides that a non-educational public agency may not disqualify a covered service for reimbursement because that service is provided in a school context.

On September 28, 2011, the Department published a notice of proposed rulemaking (NPRM) in the *Federal Register* (76 FR 60310). In the preamble, the Secretary discussed the changes proposed to the regulations that govern the use of a child's or parent's public benefits or insurance to provide or pay for services required under Part B of the IDEA.

Major Changes in the Regulations

The Department has made several significant changes to the regulations proposed in the NPRM. Specifically:

- We have added new § 300.154(d)(2)(iv), which clarifies the parental consent a public agency must obtain prior to accessing a child's or parent's public benefits or insurance for

the first time. Paragraph (A) of new § 300.154(d)(2)(iv) describes the specific elements of the written parental consent that a public agency must obtain under FERPA and IDEA before it may release for billing purposes a child's personally identifiable information to a public benefits or insurance program (e.g., Medicaid). Paragraph (B) of new § 300.154(d)(2)(iv) requires that the one-time consent described in new § 300.154(d)(2)(iv)(A) must specify that the parent understands and agrees that the public agency may access the child's or parent's public benefits or insurance to pay for services under part 300.

- Because we have added the parental consent provision in new § 300.154(d)(2)(iv), we have moved the provision requiring public agencies to provide written notification to the child's parents in proposed § 300.154(d)(2)(iv) to new § 300.154(d)(2)(v). This new paragraph incorporates, with some minor modifications from the proposed regulations, the specific information that must be included in this written notification. In addition final § 300.154(d)(2)(v) requires that the public agency provide this written notification to the child's parents both prior to accessing a child's or parent's public benefits or insurance for the first time, and annually thereafter. The Department's rationale for these changes is discussed in the *Analysis of Comments and Changes* section of this preamble.

Analysis of Comments and Changes*Introduction*

In response to the invitation in the NPRM, more than 500 parties submitted comments. An analysis of the comments and of the changes we made to the regulations as a result follows this introduction. The perspectives of parents, individuals with disabilities, State and local education officials, advocacy organizations, and others were useful in helping us identify and formulate these changes.

We discuss substantive issues under the sections of the regulations to which they pertain. The analysis generally does not address—

(a) Minor changes, including technical changes made to the language published in the NPRM;

(b) Suggested changes the Secretary is not legally authorized to make under applicable statutory authority; and

(c) Comments that express concerns of a general nature about the Department or other matters that are not directly relevant to these regulations, including requests for information about the

provision of special education and related services and other matters that are within the purview of State and local decision-makers.

Methods of Ensuring Services
(§ 300.154)

Nature of Public Benefits or Insurance Programs

Comment: One commenter requested clarification on the meaning of the phrase “seeking to bill or otherwise access the Medicaid or other public benefits or insurance programs in which a child participates to provide or pay for services required under Part B of the Act” in the preamble of the NPRM.

Discussion: We interpret the comment as a request to clarify the phrase “other public benefits or insurance programs.” The names of public benefits or insurance programs may vary across States. Generally, these programs are associated with the State agency that is responsible for the administration of a State’s Medicaid program, which is a source of funding for medically necessary school-based services that are covered benefits under Medicaid. Another example of a public benefits or insurance program is the Children’s Health Insurance Program (CHIP). These final regulations apply to all public benefits and insurance programs regardless of whether they are Medicaid programs.

All of these programs provide sources of funding for public agencies to pay for services required under part 300, provided certain conditions are met. Specifically, provided the conditions described in new § 300.154(d)(2)(iv) and (v) for obtaining parental consent and providing written notification to the child’s parents are met, public agencies may access benefits from these programs to bill for services provided by the LEA that are required under Part B of the Act.

We note that in some States, public benefits or insurance programs may also be the provider of services that are required under part 300 and are included in the individualized education programs (IEPs) of children with disabilities. In these situations the public agency would use the public benefits or insurance program to pay for those services. However, the parental consent required under FERPA and § 300.622 that is described in new § 300.154(d)(2)(iv)(A) and the written notification to the child’s parents required in new § 300.154(d)(2)(v) would apply only if the public agency seeks to access funds under the public benefits or insurance program for billing

purposes to pay for services required under part 300.

Changes: None.

Parental Consent

Comment: Many commenters supported removing the requirement in current § 300.154(d)(2)(iv)(A) that a public agency obtain parental consent each time it seeks access to public benefits or insurance. The commenters stated that eliminating this requirement would reduce paperwork and simplify the process for public agencies to access a child’s or parent’s public benefits or insurance. Other commenters expressed concern that eliminating the parental consent requirement would diminish parental rights. Another commenter requested that the regulations be revised to require consent to access a child’s or parent’s public benefits or insurance once every three years.

Discussion: We continue to believe that current § 300.154(d)(2)(iv)(A) should be removed. As we discussed in the NPRM, this change will help alleviate the burden on public agencies to obtain parental consent each time they seek to access public benefits or insurance, and will result in a more streamlined process for accessing a child’s or parent’s public benefits or insurance to pay for services provided under Part B of the Act. With the changes we are making in these final regulations, we do not believe removing this requirement will result in diminished protections for parents and children. Nor do we believe that requesting periodic consent every three years, as suggested by one commenter, would provide additional protection for parents. A periodic consent would apply only to the services that would be billed to the child’s or parent’s public benefits or insurance at the time that the parent’s consent is sought. Therefore, if a service billed to the child’s or parent’s public benefits or insurance changes within the three year period, the consent would not apply to the additional services.

Changes: None.

Comment: Some commenters requested clarification about the parental consent requirements in 34 CFR part 99 and § 300.622 and asked how those requirements would apply to the use of public benefits or insurance to pay for special education and related services. Some commenters recommended that the proposed regulations be revised to require a public agency to obtain an initial, one-time, informed consent to access a child’s or parent’s public benefits or insurance in addition to the consent already required under 34 CFR part 99

and § 300.622 to release personally identifiable information to a public benefits or insurance program. These commenters stated that this one-time, initial consent would offer more protection for families than the consent required under 34 CFR part 99 and § 300.622 alone because the one-time consent would ensure that there is an ongoing dialogue between the school district and the parents on the use of their public insurance.

Discussion: We agree with commenters who suggested that it would be helpful to clarify the parental consent requirements in 34 CFR part 99 and § 300.622 in the final regulations. We referenced these requirements in the proposed regulations in § 300.154(d)(2)(iv)(A) when we discussed the elements of written notification to be provided to parents, but the reference was very brief. Therefore, we are providing in new § 300.154(d)(2)(iv)(A) that the parental consent must meet the requirements in 34 CFR 99.30 and § 300.622 prior to accessing a child’s or parent’s public benefits or insurance for the first time. And, to clarify what is required under these provisions, and thereby ensure that the public agency provides the parents all relevant information they need to make an informed decision, we are providing in new § 300.154(d)(2)(iv)(A) that such consent must specify the personally identifiable information that may be disclosed (e.g., records or information about the services that may be provided to a particular child), the purpose of the disclosure (e.g., billing for services under part 300), and the agency to which the disclosure may be made (e.g., the State’s public benefits or insurance program (e.g., Medicaid)). We believe these changes will clarify the parental consent that must be obtained under 34 CFR 99.30 and § 300.622 before a public agency discloses, for billing purposes, the child’s personally identifiable information to the agency responsible for the administration of the State’s public benefits or insurance program (e.g., Medicaid) prior to accessing a child’s or parent’s public benefits or insurance for the first time to pay for services required under part 300.

To ensure that a parent fully understands that the purpose of the consent obtained under 34 CFR part 99 and § 300.622 is to enable the public agency to access the child’s or parent’s public benefits or insurance for the first time and in the future, we are adding new § 300.154(d)(2)(iv)(B). This section provides that the consent to access public benefits or insurance must state that the parent understands and agrees

that the public agency may access the child's or parent's public benefits or insurance to pay for services under part 300. We note that to comply with the new parental consent requirement in final § 300.154(d)(2)(iv)(B), a public agency may add the specific statement included in new § 300.154(d)(2)(iv)(B) to the consent required under 34 CFR 99.30 and § 300.622 to release personally identifiable information to a public benefits or insurance program (e.g., Medicaid) for billing purposes, or it may choose to obtain this consent statement separately.

Further, to help ensure that a parent understands his or her rights when a public agency seeks to use or uses their or their child's public benefits or insurance to pay for services under part 300 we are also specifying in § 300.154(d)(2)(iv)(A) that the public agency must provide the written notification described in final § 300.154(d)(2)(v) (proposed § 300.154(d)(2)(iv)) before obtaining parental consent.

Changes: We have revised the regulations to add a new § 300.154(d)(2)(iv). In final § 300.154(d)(2)(iv), we have clarified that parental consent must be obtained before a public agency accesses a child's or parent's public benefits or insurance for the first time.

We have specified that the public agency must provide written notification to the child's parents consistent with § 300.154(d)(2)(v) before parental consent is obtained.

We have added new paragraph (d)(2)(iv)(A) to describe the parental consent required by 34 CFR 99.30 and § 300.622 that a public agency must obtain prior to disclosing for billing purposes a child's personally identifiable information to a State's public benefits or insurance before accessing a child's or parent's public benefits or insurance for the first time.

We have added new § 300.154(d)(2)(iv)(B) to require that the consent must specify that the parent understands and agrees that the public agency may access the child's or parent's public benefits or insurance to pay for services under part 300.

Comment: A few commenters asked whether a public agency must obtain a new consent following the publication of the final regulations if the agency already has a parent's consent on file.

Discussion: As described below, under these final regulations, a new consent is not necessary provided there is no change in any of the following: the type (e.g., physical therapy or speech therapy) of services to be provided to the child; the amount of services to be

provided to the child (frequency or duration); or the amount that the public agency charges to the public benefits or insurance program.

Under current regulations, a public agency is required to obtain parental consent to access a child's or parent's public benefits or insurance to bill for specific services. Current § 300.154(d)(2)(iv)(A) provides that consistent with the definition of "consent" in § 300.9(b), the parent understands and agrees in writing to the carrying out of the activity for which his or her consent was sought. The consent must describe the activity, the records (if any) that were released, and the entity to whom the records were released. Therefore, a public agency that has on file a parental consent that meets the requirements of current § 300.154(d)(2)(iv)(A) and 34 CFR 99.30 and § 300.622 will not be required to obtain a new parental consent following the publication of these final regulations, as long as the type or amount of services that the public agency will bill to public insurance or the amount that the public agency charges to the public benefits or insurance program does not change. By previously consenting, the parent understood and agreed that the public agency was accessing the child's or parent's public benefits or insurance (e.g., Medicaid) to pay for a specified type, amount, and cost of services under part 300.

However, for children for whom the public agency already has consent under current § 300.154(d)(2)(iv)(A), the first time after the effective date of these regulations that there is a change in the type or amount of services to be provided, or the amount charged by the public agency or cost of services billed to the public benefits or insurance program, the public agency must provide the parents the written notification described in new § 300.154(d)(2)(v). The public agency must also obtain consent, consistent with new § 300.154(d)(2)(iv)(B), stating that the parent understands and agrees to the public agency's accessing the child's or parent's public benefits or insurance to pay for services under part 300. Once the public agency obtains this one-time consent, the public agency will not be required to obtain any further parental consent in the future before it accesses the child's or parent's public benefits or insurance, regardless of whether there is any change in the type, amount, or cost of services to be billed to the public benefits or insurance program (e.g., Medicaid). However, the public agency will annually thereafter be required to provide parents with the

written notification described in final § 300.154(d)(2)(v), to help ensure that parents understand their rights when a public agency uses their or their child's public benefits or insurance to pay for services under part 300.

Of course, with respect to children with disabilities who receive special education and related services that were not previously billed to the child's or parent's public benefits or insurance program (e.g., Medicaid), a public agency must provide the child's parents the written notification described in new § 300.154(d)(2)(v) and obtain parental consent in accordance with final § 300.154(d)(2)(iv)(A) and (B) prior to accessing the child's or parent's public benefits or insurance (e.g., Medicaid) for the first time to pay for services under part 300. This parental consent must meet the requirements in 34 CFR 99.30 and § 300.622 that apply prior to the release of the child's personally identifiable information to the public benefits or insurance program (e.g., Medicaid) for billing purposes. The consent must also include a statement specifying that the parent understands and agrees that the public agency may access the child's or parent's public benefits or insurance to pay for services under part 300.

Changes: None.

Comment: Some commenters asked for clarification regarding the Department's position in the March 8, 2007, letter to Mr. John Hill, particularly in situations when parental consent is given directly to another agency, such as the State Medicaid agency.

Discussion: Our position has not changed from what it was in the March 8, 2007, letter to Mr. John Hill. See <http://www2.ed.gov/policy/speced/guid/idea/letters/2007-1/hill030807consent1q2007.pdf>. The public agency is not required to independently obtain separate parental consent, so long as the parental consent provided to the other agency meets the requirements of 34 CFR 99.30 and § 300.622, and current § 300.154(d)(2)(iv)(A) and there is no change in the type, amount, or cost of services to be billed to the public insurance program. However, if the type, amount, or cost of services to be billed to the public benefits or insurance program changes, the public agency must provide to the parent the written notification described in new § 300.154(d)(2)(v) (proposed § 300.154(d)(2)(iv)) and obtain parental consent on a one-time basis in accordance with new § 300.154(d)(2)(iv)(B). This consent must specify that the parent understands and agrees that the public agency may access the child's or

parent's public benefits or insurance to pay for services under part 300.

Changes: None.

Comment: One commenter requested the word "informed" be placed in front of the word "consent" in the final regulations.

Discussion: We do not believe this change is necessary for the reasons explained in response to the comments regarding the parental consent provisions and the written notification requirement. We believe that the consent required by these final regulations is informed consent. Parents understand that they are consenting to enable the public agency to access their or their child's public benefits or insurance (e.g., Medicaid) to pay for services under part 300.

Changes: None.

Comment: One commenter questioned the value of the proposed regulatory change if school districts will have to obtain parental consent to be able to provide the child's personally identifiable information prior to submitting that information to Medicaid. Other commenters asked the Department to eliminate any requirements to obtain parental consent for Medicaid reimbursable services. These commenters asserted that IDEA contains no requirement to obtain consent before a public agency seeks reimbursement for Medicaid-eligible services to Medicaid-eligible children. The commenters also asserted that other non-school Medicaid providers are permitted to seek reimbursement for Medicaid-eligible services to Medicaid-eligible individuals, including school age children, without seeking parental consent.

Discussion: Under these final regulations, educational agencies covered by 34 CFR part 99 and public agencies under the IDEA must continue to adhere to the consent requirements in 34 CFR 99.30 and § 300.622, which we describe in new § 300.154(d)(2)(iv)(A). Under FERPA and section 617(c) of the Act, a public agency may not release personally identifiable information from a child's education records to a public benefits or insurance program without prior parental consent, except for a few specified exceptions that do not include the release of education records for billing purposes. Therefore, final § 300.154(d)(2)(iv)(A) describes the parental consent that is required under 34 CFR 99.30 and § 300.622 before a public agency may release personally identifiable information from education records for billing purposes to a public benefits or insurance program prior to accessing a child's or parent's public benefits or insurance for the first time.

Additionally, new § 300.154(d)(2)(iv)(B) requires a one-time consent specifying that the parent understands and agrees that the public agency may access the child's or parent's public benefits or insurance to pay for services under part 300. We believe that these final regulations continue to protect a parent's rights under FERPA and confidentiality rights under IDEA, and they address concerns from public agencies about costs and the administrative burden associated with obtaining parental consent each time access to public benefits insurance is sought.

Changes: None.

Comment: A few commenters recommended that we retain the current regulations and require parental consent each time a public agency seeks access to Medicaid or other public benefits or insurance programs in order to hold schools accountable for what they bill to the State Medicaid program and to facilitate better communication between the school and parent.

Discussion: We do not believe that it is necessary to retain the current parental consent requirement in order to hold schools accountable for services they bill to public insurance programs (e.g., Medicaid). We believe the parental consent required in 34 CFR 99.30 and § 300.622 (now described in new § 300.154(d)(2)(iv)(A)) and in new § 300.154(d)(2)(iv)(B) will provide sufficient communication with and protection for parents while making it easier for public agencies to access those benefits or insurance to pay for services required under part 300. The former is required before disclosing a child's personally identifiable information to a State's public benefits or insurance program (e.g., Medicaid) for billing purposes. The latter requires that the parent understands and agrees that a public agency may access their or their child's public benefits or insurance to pay for services required under part 300.

In addition to the parental protections provided for in these final regulations, a State's Medicaid agency or other public benefits or insurance program is already responsible for monitoring schools and LEAs to ensure that children are receiving the services for which the public agency bills the public benefits or insurance program. Of course, if a public agency that accesses a child's or parent's public benefits or insurance to pay for required services does not provide those services at no cost to the parents, an SEA must use its general supervisory authority under § 300.149 to achieve compliance. This authority requires each SEA to ensure that all educational programs for

children with disabilities administered within the State meet State education standards and the requirements of the Act and part 300. Pursuant to §§ 300.149(b) and 300.600, an SEA must monitor public agencies' implementation of the Act and Part B regulations and ensure timely correction of any identified noncompliance. Also, parents may use IDEA's dispute resolution mechanisms to raise concerns regarding the denial of appropriate services at no cost to the parents. These mechanisms include mediation under § 300.506, due process complaint procedures under §§ 300.507 through 300.516, and State complaint procedures under §§ 300.151 through 300.153. Further, a parent or an organization or individual other than the child's parents, including one from another State, may file a signed, written complaint alleging a violation of Part B of the Act or the Part B regulations. We believe all of these protections help to ensure public agency accountability under the IDEA.

The Secretary also believes that the changes we are making in these final regulations will improve communication between the school and parents. Requiring written notification to the child's parents, consistent with new § 300.154(d)(2)(v), before a public agency obtains consent will provide important information that school districts were not required to provide parents in the past. This includes information about the parental consent requirements in final § 300.154(d)(2)(iv) and a parent's right to withdraw consent at any time.

Changes: None.

Comment: One commenter asked whether the public agency may ask a parent for permission to disclose personally identifiable information to the State public benefits or insurance program if the parent previously declined to provide consent for such disclosure.

Discussion: As in the past, a public agency may make reasonable requests to obtain the parental consent required under new § 300.154(d)(2)(iv) from a parent who previously declined to provide consent to disclose personally identifiable information to the State's public benefits or insurance program (e.g., Medicaid) for billing purposes to pay for services required under part 300. Prior to seeking to obtain this parental consent, the public agency must provide the parents with written notification consistent with new § 300.154(d)(2)(iv).

Changes: None.

Comment: One commenter recommended that the regulations include guidance on whether new

parental consent needs to be obtained prior to disclosing personally identifiable information to access a child's or parent's public benefits or insurance when consent is obtained in one school district, but the child subsequently relocates to another school district within the State or to a location outside of the State.

Discussion: Under § 300.323(e) through (g), States must have policies and procedures in effect to govern IEPs for students who transfer from one public agency to another, and we believe that those policies and procedures could address the parental consent and written notification requirements that apply to accessing public benefits or insurance for billing purposes for services required under part 300 for children who relocate to another public agency or another State. The responsibility for obtaining parental consent prior to the disclosure of personally identifiable information for billing purposes and before accessing a child's or parent's public benefits or insurance for the first time rests with the public agency responsible for providing a free appropriate public education (FAPE) to the child, not with the individual school. Thus, if a child who had an IEP in effect in a previous public agency transfers to a school in a new public agency in the same school year, whether or not within the same State, the new public agency would need to obtain a new parental consent under new § 300.154(d)(2)(iv)(A)–(B) before it can access the child's or parent's public benefits or insurance for the first time to pay for services under part 300. This new parental consent is to enable the new public agency to release the child's personally identifiable information for billing purposes to the public benefits or insurance program (e.g., Medicaid). Consistent with new § 300.154(d)(2)(iv)(B), the consent also must specify that the parent understands and agrees that the new public agency may access the child's or parent's public benefits or insurance to pay for services under part 300. Likewise, in these transfer situations, the new public agency must provide the child's parents with the written notification described in final § 300.154(d)(2)(v) prior to obtaining parental consent for that agency to access the child's or parent's public benefits or insurance for the first time. Further, the new public agency must provide this written notification to the child's parents annually thereafter. However, if a child transfers to a different school but remains within the

same public agency, any parental consent that the public agency has previously obtained that meets the requirements in new § 300.154(d)(2)(iv)(A)–(B) would continue to apply.

Changes: None.

Comment: One commenter recommended that electronic signatures for consent be accepted as valid due to the increasing use of virtual meetings.

Discussion: A public agency may accept digital or electronic signatures in obtaining the parental consent required under 34 CFR 99.30 and § 300.622, as described in new § 300.154(d)(2)(iv)(A), before disclosing, for billing purposes, the child's personally identifiable information to the agency responsible for the administration of the State's public benefits or insurance program (e.g., Medicaid) prior to accessing the child's or parent's public benefits or insurance for the first time. Among other requirements, under 34 CFR 99.30(a), the parental consent that must be obtained before disclosure of personally identifiable information must be signed and dated. Section 99.30(d) provides that this consent may include a record and signature in electronic form that—

- (1) Identifies and authenticates a particular person as the source of the electronic consent; and
- (2) Indicates such person's approval of the information contained in the electronic consent, i.e., disclosure of the child's personally identifiable information to the agency responsible for the administration of the State's public benefits or insurance program (e.g., Medicaid) for billing purposes to pay for services under part 300. Additionally, the electronic consent must include a statement that the parent understands and agrees that the public agency may access the child's or parent's public benefits or insurance to pay for services under part 300.

Changes: None.

Parental Notification

Comment: Many commenters supported the requirement in proposed § 300.154(d)(2)(iv) that prior to accessing a child's or parent's public benefits or insurance, the public agency must provide written notification to parents consistent with current § 300.503(c). Several commenters stated that this type of written notification would help to protect children's and parents' rights under IDEA and FERPA. These commenters agreed with the Department's analysis in the NPRM that the proposed written notification requirement would provide parents with important information they need to

understand their rights in the special education process. They also stated that the proposed requirement would ensure that all parents of children with disabilities receive full disclosure of their rights on the use of their public benefits or insurance for services under Part B, particularly their rights under FERPA and the IDEA confidentiality requirements.

A few commenters recommended that the written notification in proposed § 300.154(d)(2)(iv) be provided at the child's initial IEP Team meeting. Another commenter expressed concern that providing the written notification at the initial IEP Team meeting would overwhelm parents. Some commenters suggested that LEAs be given discretion on when to provide the notification. One commenter asked if the proposed parental written notification may be mailed to the parents.

Several commenters expressed concern about only providing parents with a one-time written notification. They instead recommended that a written notification be provided to parents at each subsequent annual IEP Team meeting and when there is an amendment to the IEP during the course of the school year that would result in a change to the type or amount of services billed to a public benefits or insurance program. These commenters stated that requiring more frequent written notifications would provide parents with greater protections and remind parents that they can reconsider their consent in light of changed circumstances a family may experience over time (e.g., change in the child's disability, change in living situation, change in guardianship, etc.).

Discussion: The Department appreciates the commenters' strong support for the written notification provision in proposed § 300.154(d)(2)(iv) and has retained this provision in new § 300.154(d)(2)(v) with a few minor modifications. We agree with commenters generally that more frequent notifications to the child's parents in addition to the initial written notification to the child's parents would be beneficial. Therefore, we are amending new § 300.154(d)(2)(v) (proposed § 300.154(d)(2)(iv)) to require that the public agency provide written notification that meets the requirements of § 300.503(c) to the child's parents prior to accessing a child's or parent's public benefits or insurance for the first time and annually thereafter. The requirement that the notice be written in language understandable to the general public and in the native language of the parent or other mode of communication used by the parent, unless it is clearly

not feasible to do so, will provide additional protections for children and parents. This annual written notification will be especially important for parents in families that experience a change in circumstances over time and for children whose parent, as defined in § 300.30, changes often (e.g., children in the foster care system), children whose guardianship changes, or children who live with an individual acting in place of the biological or adoptive parent. Providing an annual written notification to parents also will serve to remind them of important safeguards previously explained. Further, as discussed earlier, we are specifying in final § 300.154(d)(2)(iv) that this written notification must be provided to the child's parents before the public agency obtains their consent to access their or their child's public benefits or insurance for the first time.

In those instances where a child has been determined eligible for Medicaid prior to the IEP Team meeting, the public agency could provide the child's parents with the written notification described in final § 300.154(d)(2)(v) at the IEP Team meeting or at some other meeting, so long as the child's parents receive the written notification before the public agency obtains the requisite parental consent under final § 300.154(d)(2)(iv) to access the parent or child's public benefits or insurance for the first time.

We do not agree with those commenters who recommended requiring the written notification described in proposed § 300.154(d)(2)(iv) be provided at the child's initial IEP Team meeting or at subsequent IEP Team meetings. We appreciate the importance of parent participation in the IEP process, and we recognize that an IEP Team meeting could provide a public agency with a meaningful opportunity to explain to the parents the components of the written notification and respond to any questions the parents may have.

As a practical matter, however, eligibility for Medicaid may not necessarily coincide with annual IEP Team meetings. Therefore, requiring written notification at an IEP Team meeting could mean that a public agency would have to convene an additional IEP Team meeting for those children found to be eligible for Medicaid only after the annual IEP Team meeting.

We also do not agree with the commenters who suggested that written notification be provided each time the public agency amends a child's IEP in a manner that would result in a change to the type or amount of services billed

to the public benefits or insurance program. We believe that providing parents the annual written notification in accordance with final § 300.154(d)(2)(v) is sufficient protection in these situations. Of course, nothing in these regulations would prevent public agencies from providing parents the written notification described in final § 300.154(d)(2)(v) more frequently than annually, if they deem it appropriate to do so. Further, nothing in these regulations would prevent public agencies from providing the notification described in final § 300.154(d)(2)(v) to all parents of children with disabilities, regardless of whether the public agency is seeking to access the child's or parent's public benefits or insurance.

There are a number of ways in which the public agency may provide the written notification to parents. The annual written notification may be mailed to the parents, provided at an IEP Team meeting if it occurs prior to the first time a public agency accesses a child's or parent's public benefits or insurance, or provided through other means determined by the public agency, so long as all of the written notification requirements in these final regulations are met, including the requirement in § 300.154(d)(2)(v) that the public agency provide written notification before obtaining parental consent under new § 300.154(d)(2)(iv).

We decline to specify in the regulations when subsequent annual written notifications must be provided to parents because we believe that once the public agency provides the child's parents the written notification described in final § 300.154(d)(2)(v) prior to accessing the child's or parent's public benefits or insurance for the first time, public agencies need to have the flexibility to determine the timing of subsequent annual written notifications.

Finally, for those children with IEPs for whom services have previously been billed to Medicaid, when the final regulations become effective, the written notification requirement in final § 300.154(d)(2)(v) applies. The written notification, therefore, must be provided before the public agency may access the child's or parent's public benefits or insurance after these final regulations become effective and annually thereafter. As noted previously, no new parental consent would need to be obtained if there is no change in the type, amount, or cost of services to be billed to public benefits or insurance (e.g., Medicaid).

However, in the future, if the type, amount, or cost of services billed to the public benefits or insurance program

changes, the public agency must provide to the parent the written notification described in new § 300.154(d)(2)(v) (proposed § 300.154(d)(2)(iv)) before obtaining one-time parental consent in accordance with new § 300.154(d)(2)(iv)(B) specifying that the parent understands and agrees that the public agency may access the child's or parent's public benefits or insurance to pay for services under part 300 in the future.

Changes: We have revised final § 300.154(d)(2)(v) to specify that the written notification must be provided to the child's parents prior to accessing a child's or parent's public benefits or insurance for the first time and annually thereafter. To conform to the changes in new § 300.154(d)(2)(iv), we have added a reference in new § 300.154(d)(2)(v)(A) to the new regulatory provision regarding parental consent in § 300.154(d)(2)(iv).

We have also revised new § 300.154(d)(2)(v)(C) (proposed § 300.154(d)(2)(iv)(C)) to clarify that parents may withdraw their consent under part 99 and part 300 to the disclosure of their child's personally identifiable information to the agency responsible for the administration of the public benefits or insurance program (e.g., Medicaid). The reference to part 300 was inadvertently left out of proposed § 300.154(d)(2)(iv)(C). We also have renumbered paragraphs (B) and (D) of the proposed regulations with no other changes.

Comment: One commenter recommended that the written notification provided to parents clearly and prominently provide information to parents about the process of withdrawing consent for disclosure of personally identifiable information necessary to access public insurance.

Discussion: Proposed § 300.154(d)(2)(v)(C) provided that the written notification to the child's parents had to include a statement that parents have the right under 34 CFR part 99 to withdraw their consent to the disclosure of their child's personally identifiable information to the agency responsible for the administration of the State's public benefits or insurance program (e.g., Medicaid) at any time. This provision has been retained in final § 300.154(d)(2)(v)(C), but as noted in the response to comments about the timing of the written notification, this section has been revised to also include a reference to withdrawal of consent under part 300. The parents must be informed of this right in the written notification that the public agency must provide them prior to accessing their or their child's public benefits or insurance

for the first time and annually thereafter.

FERPA and IDEA do not include specific provisions regarding the process for withdrawal of consent for the disclosure of a child's personally identifiable information; therefore, we are deferring to LEAs on procedures for withdrawal of this parental consent. However, once the parent withdraws consent under 34 CFR part 99 and part 300 to the disclosure of the child's personally identifiable information to the agency responsible for the administration of the State's public benefits or insurance program (e.g., Medicaid), the public agency responsible for providing FAPE to the child with a disability may no longer bill the public benefits or insurance program (e.g., Medicaid) to pay for services under part 300. The public agency must nevertheless continue to provide the child with all services required under part 300 at no cost to the parents.

Changes: None.

Comment: A few commenters asked whether the proposed written notification takes the place of written parental consent for a child to participate in Medicaid-funded related services at school, particularly in a State where the public agency provides the child's IEP to the public benefits or insurance program so that the public benefits or insurance program may determine whether the related services are medically necessary and covered under the public benefits or insurance program.

Discussion: The final regulations are clear that the written notification requirement in final § 300.154(d)(2)(v) is separate and distinct from, and does not replace, the parental consent requirements in FERPA and IDEA that are now described in new § 300.154(d)(2)(iv)(A). Further, under new § 300.154(d)(2)(iv)(B), this parental consent must specify that the parent understands and agrees that the public agency may access the child's or parent's public benefits or insurance to pay for services under part 300. The written notification requirements in final § 300.154(d)(2)(v) (proposed § 300.154(d)(2)(iv)) continue to underscore the significance of those requirements and now require that this written notification include an explanation of the parental consent requirements contained in new § 300.154(d)(2)(iv)(A)–(B).

These requirements continue to apply even in States where the public agency provides the IEP to the public benefits program to verify that the related services in the IEP are medically

necessary and covered under the public benefits or insurance program. The consent required in this context must be obtained before the public agency accesses the child's or parent's public benefits or insurance for the first time to bill for services required under part 300 and after the public agency provides the written notification described in new § 300.154(d)(2)(v). Further, this consent must specify that the parent understands and agrees that the public agency may access the parent's or child's public benefits or insurance to pay for services under part 300.

We remind public agencies that they may not reduce or delay providing the services in a child's IEP solely because the State's public benefits or insurance program determined that the services required in the child's IEP are not medically necessary or not covered under the public benefits or insurance program. If the services are not medically necessary under Medicaid, a public agency would not receive reimbursement for them. But the public agency is not relieved of its responsibility under Part B to ensure that all required services in the IEP are provided at no cost to the parents, even if that means using Part B funds or sources of support other than the child's or parent's public benefits or insurance in order to ensure that the child receives all required services at no cost to the parents.

Changes: None.

Comment: A few commenters requested model language for the written notification requirement.

Discussion: Following the publication of these final regulations, the Department intends to issue model language for the written notification requirement described in final § 300.154(d)(2)(v).

Changes: None.

Other Matters

Comment: A few commenters stated that public agencies should not be permitted to bill Medicaid for educational services because this would deplete medical benefits that should be directed to families. Other commenters, concerned about the potential for Medicaid fraud, recommended that parents who consent to the use of Medicaid funds to pay for their child's school-based health services should be provided a quarterly statement of those services. Another commenter asked whether Medicaid may be billed for services the child does not receive.

Discussion: These final regulations continue to permit public agencies to use Medicaid or other public benefits or insurance to provide or pay for services

required under part 300, provided that those agencies comply with the consent requirements in 34 CFR 99.30 and § 300.622, now described in final § 300.154(d)(2)(iv)(A), including the requirement that parents provide their consent prior to the release of their child's personally identifiable information to the public benefits or insurance program for billing purposes before the public agency may access the parent's or child's public benefits or insurance for the first time. This consent must also specify that the parent understands and agrees that the public agency may access the child's or parent's public benefits or insurance to pay for services under part 300. Public benefits and insurance are important sources of financial support for services required under Part B. Section 612(a)(12) of the Act requires the State to identify or have a method of defining the financial responsibility of non-educational public agencies for services required to provide FAPE to children with disabilities and that the financial responsibility of those non-educational public agencies, including the State Medicaid agency and other public insurers of children with disabilities, must precede the financial responsibility of LEAs or the State agency responsible for developing the child's IEP. The statute, therefore, contemplates that public agencies responsible for providing education to children with disabilities under State law, in appropriate circumstances, access funds from public benefits and insurance programs (e.g., Medicaid) as a means of paying for services required under Part B.

We do not believe it is necessary to require public agencies to provide quarterly statements of the dates and times children with disabilities are provided school-based health services. However, under § 300.613 each participating agency must permit parents to inspect and review any education records relating to their child that are collected, maintained, or used by the agency to implement Part B of the Act. A parent, therefore, may request to review any education records relating to their child that have been sent to the State public benefits or insurance program.

If parents believe public agencies are billing Medicaid for services that their child does not receive, they should file a complaint with the State agency responsible for the administration of the State's Medicaid program. The Department has no jurisdiction over complaints alleging Medicaid fraud. However, if a parent believes that a public agency has not provided his or

her child all required services at no cost to the parents, this could constitute a denial of FAPE under the Act and these regulations, and the parent could use IDEA's dispute resolution mechanisms to seek redress. These mechanisms include mediation under § 300.506, the due process complaint procedures in §§ 300.507 through 300.516, or the State complaint procedures in §§ 300.151 through 300.153. Note also that under the State complaint procedures in §§ 300.151 through 300.153, any organization or individual other than the child's parent, including one from another State, may file a signed, written complaint alleging that a public agency has violated a requirement of Part B of the Act or the Part B regulations.

Changes: None.

Comment: A few commenters recommended that LEAs be included in the consent language on the Medicaid application form used in most States. The commenters stated that like hospitals and clinics, schools are providers of Medicaid services and do not need a separate consent form. One commenter requested that the written notice include a warning to parents that once in receipt of public benefits or insurance, the subsequent refusal to share such information with the Medicaid program is a violation of the terms of eligibility and is in many States considered a crime.

Discussion: The Department does not administer Medicaid or other State public benefits or insurance programs and, therefore, cannot dictate what States choose to include on applications or how State programs choose to address parties that do not share required information with them. Under new § 300.154(d)(2)(iv), if parents refuse to consent to release personally identifiable information to a public benefits or insurance program for billing purposes under 34 CFR 99.30 and § 300.622, the public agency may not access the child's or parents public benefits or insurance to pay for those services, and the child with a disability must continue to receive all special education and related services necessary for the provision of FAPE at no cost to the parents.

Changes: None.

Comment: A few commenters asked the Department to clarify whether the proposed regulations apply to the use of private insurance to pay for services to children with disabilities. One commenter expressed concern that under the proposed regulations, a family's right to privacy is linked to its economic status. Other commenters expressed concern that the regulations establish a dual standard for consent

based on whether the child or parent is enrolled in a private insurance program or a public benefits or insurance program.

Discussion: Final § 300.154(d)(2)(iv)–(v) applies only to public benefits and insurance programs and does not apply to private insurance programs. The requirements for children with disabilities covered by private insurance are found in § 300.154(e). For services required to provide FAPE to an eligible child under Part B of the Act, a public agency may access the parents' private insurance proceeds only if the parents provide consent consistent with § 300.9. Each time the public agency proposes to access the parents' private insurance, the agency must obtain parental consent and inform the parents that their refusal to permit the public agency to access their private insurance does not relieve the public agency of its responsibility to ensure that all required services are provided at no cost to the parents.

We disagree with the comments that the proposed regulations set a dual standard based on economic status and enrollment in private versus public insurance. The Act places no financial obligations on private insurers; however, section 612(a)(12) of the Act places financial obligations on non-educational public agencies by requiring States to identify or have a method of defining the financial responsibility of non-educational public agencies, including the State Medicaid agency and other public insurers of children with disabilities, for services provided by the LEA that are necessary to provide FAPE to children with disabilities. No similar statutory provision exists regarding the use of private insurance. In addition, section 612(a)(12) of the Act requires that the financial responsibility of those non-educational public agencies, including the State Medicaid agency and other public insurers of children with disabilities, must precede the financial responsibility of an LEA or the State agency responsible for developing the child's IEP. This statutory provision also requires non-educational public agencies, such as a State Medicaid agency, to fulfill their obligations or responsibilities under State or Federal law to pay for services provided by LEAs required under Part B, if permitted under the public benefits or insurance program. To the extent that the final regulations treat people who have public and private insurance differently, the regulations merely reflect the operation of the Act.

These final regulations are consistent with the Act and strengthen the privacy and confidentiality protections afforded to parents and children enrolled in

public benefits or insurance programs who are eligible to receive special education and related services under Part B of the Act. For example, new § 300.154(d)(2)(iv)(A) requires a public agency to obtain the parental consent required in § 300.622 and 34 CFR 99.30 before the agency accesses a child's or parent's public benefits or insurance for the first time. Additionally, final § 300.154(d)(2)(iv)(B) provides that this consent must specify that the parent understands and agrees that the public agency may access a child's or parent's public benefits or insurance to pay for services under part 300. Further, in accordance with final § 300.154(d)(2)(v), the public agency must provide the child's parents with written notification consistent with § 300.503(c) prior to obtaining parental consent to access a child's or parent's public benefits or insurance for the first time. A public agency must also provide this written notification annually thereafter. This written notification must inform the child's parents in language understandable to the general public and in the parent's native language or other mode of communication used by the parent, unless it is clearly not feasible to do so, of the following:

(a) A statement of the parental consent provisions in § 300.154(d)(2)(iv)(A)–(B).

(b) A statement of the "no cost" provisions under § 300.154(d)(2)(i)–(iii).

(c) A statement that parents have the right under 34 CFR part 99 and part 300 to withdraw their consent to disclosure of their child's personally identifiable information to the agency responsible for the administration of the State's public benefits or insurance program (e.g., Medicaid) at any time.

(d) A statement that withdrawal of consent or refusal to provide consent under 34 CFR part 99 and part 300 to disclosure of personally identifiable information to the agency responsible for the administration of the State's public benefits or insurance program (e.g., Medicaid) does not relieve the public agency of its responsibility to ensure that all required services are provided at no cost to the parents.

We believe these parental consent and written notification requirements will strengthen the protections afforded to parents and children enrolled in public benefits or insurance programs by specifically including the parent's right to withdraw their consent under 34 CFR part 99 and part 300 at any time.

If a parent chooses to withdraw this consent, the public agency responsible for providing FAPE to the child with a disability may no longer bill the public benefits or insurance program (e.g.,

Medicaid) to pay for services required under part 300 and must ensure that the child receives all required services necessary to receive FAPE at no cost to the parents.

Changes: None.

Comment: One commenter stated that the proposed regulations would diminish the protections of FERPA and violate the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The commenter also asserted that the proposed regulations would violate the Equal Protection Clause because individuals without disabilities are not spending down their Medicaid resources and that the notice provision would violate due process.

Discussion: HIPAA is administered by the U.S. Department of Health and Human Services and not by the Department of Education. HIPAA excludes from its definition of “protected health information” individually identifiable health information contained in education records covered by FERPA and records described under FERPA’s medical treatment records provision (34 CFR 99.3, defining “education records”). See 45 CFR 160.103. Thus, the term “protected health information” in the HIPAA Privacy regulations does not cover records protected by FERPA. The reason for this exception is that Congress, through FERPA, specifically addressed how education records and student treatment records should be protected.

FERPA provides ample protections for these records, which include requiring public agencies to obtain prior consent from parents before a child’s personally identifiable information is disclosed to the agency responsible for the administration of the State’s public benefits or insurance program (e.g., Medicaid) for billing purposes. There is no exception under FERPA or under these final regulations that would permit the nonconsensual disclosure of personally identifiable information in education records to a public benefits or insurance program (e.g., Medicaid) for billing purposes. Likewise, the IDEA’s confidentiality of information provisions in section 617(c) of the Act and § 300.622 also require parental consent before personally identifiable information can be disclosed to a State’s public benefits or insurance program for billing purposes (e.g., Medicaid). Therefore, nothing in these final regulations violates or is in any way inconsistent with either HIPAA or FERPA. In fact, the final regulations support FERPA in that they require written notification to inform parents of certain protections under FERPA.

Further, neither the proposed nor final regulations violate the U.S. Constitution’s Equal Protection Clause. On the contrary, they help to ensure that children, regardless of disability status, have equal access to education. The regulations facilitate access to FAPE by removing the requirement in current regulations for a public agency to obtain consent from the parent each time access to public benefits or insurance is sought, while continuing to require that the parental consent required by FERPA and section 617(c) of the IDEA prior to disclosure of personally identifiable information for billing purposes to a State’s public benefits or insurance program, now described in final § 300.154(d)(2)(iv)(A), be obtained before a public agency can access a child’s or parent’s public benefits or insurance for the first time.

These final regulations also require that, in accordance with new § 300.154(d)(2)(iv)(B), the consent must specify that the parent understands and agrees that the public agency may access the child’s or parent’s public benefits or insurance to pay for services under part 300. Additionally, an important new protection is provided to parents through the written notification provision in new § 300.154(d)(2)(v), which must be provided to the child’s parents prior to accessing the child’s or parent’s public benefits or insurance for the first time and annually thereafter.

As in the past, these final regulations will continue to require, as specified in § 300.154(d)(2)(i) through (d)(2)(iii), that the children of parents who consent to share their children’s personally identifiable information with a State’s public benefits or insurance program (e.g., Medicaid) for billing purposes continue to receive all required services under this part at no cost.

Finally, we do not agree with the commenter’s assertion that the notice would deny due process. Rather, the written notification required in new § 300.154(d)(2)(v) would enhance due process protections for parents by providing them crucial information about when public agencies seek to access their or their child’s public benefits or insurance.

Changes: None.

Comment: One commenter requested clarification on the example provided in the NPRM discussing “Tommy” and asked whether a related services provider is required to attend the IEP Team meeting when the team discusses the related service.

Discussion: The IDEA does not expressly require that related services personnel attend IEP Team meetings. However, if a child with a disability has

an identified need for a related service, it would be appropriate for the related services provider to attend the meeting. Additionally, if the public agency designates the related services provider as a required IEP Team member, the public agency must ensure that the individual attends the child’s IEP Team meeting, unless the excusal provisions in § 300.321(e) are met.

Changes: None.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is “significant” and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of \$100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an “economically significant” rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles stated in the Executive order.

This regulatory action is a significant regulatory action subject to review by OMB under section 3(f)(4) of Executive Order 12866 because this action is economically significant.

We have also reviewed these regulations under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor their regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency “to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.” The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include “identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.”

We are issuing these regulations only on a reasoned determination that their benefits justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that these regulations are consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

Potential Costs and Benefits

The following is an analysis of the costs and benefits of the significant changes reflected in these final regulations. In conducting this analysis, the Department examined the extent the changes made by these regulations add to or reduce the costs to States, LEAs, and others, as compared to the costs of implementing the current Part B program regulations. Based on the following analysis, the Secretary has concluded that the changes reflected in the final regulations will not impose significant costs on States, LEAs, and others.

Costs and Benefits

Current Section 300.154(d)

Under current regulations, public agencies are required to obtain parental consent, consistent with § 300.9, each

time access to a child’s or parents’ public benefits or insurance is sought to pay for services identified in the child’s IEP. This has meant that written parental consent to access public benefits or insurance must be obtained for a specified type of service (e.g., physical therapy, speech therapy), and amount of services (frequency or duration). If the type, amount, or cost of service changes, the public agency must obtain new parental consent covering the change in services to be charged to the child’s or parents’ public benefits or insurance.

New § 300.154(d)(2)(iv) and (v)

The final regulations eliminate the requirement to obtain consent every time that the type or amount of service changes, or the amount charged for services changes. Instead, the final regulations require public agencies to obtain an initial, one-time consent from parents before the agency seeks to access a child’s or parent’s public benefits or insurance (e.g., Medicaid). This consent must meet the parental consent requirements under 34 CFR part 99 and § 300.622 and must specify that the parent understands and agrees that the public agency may access the child’s or parent’s public benefits or insurance to pay for services provided under part 300. This written consent is consistent with the consent currently required under § 300.9(b), which specifies that the parent understands and agrees to the carrying out of the activity for which his or her consent is sought and the records to be released and to whom. However, consent under current § 300.154(d)(2)(iv)(A) would no longer be valid if the public agency seeks to access public benefits or insurance for a different type or amount of services for a specified period of time.

The final regulations also require public agencies to specifically inform parents of their rights and protections under the Act by providing written notification prior to obtaining consent to access public benefits or insurance for the first time. This written notification also must be provided to the child’s parents annually thereafter. Thus, a public agency would be able to access a child’s or parent’s public benefits or insurance program to provide or pay for services required under Part B of the Act without obtaining parental consent each time it seeks access, provided that (1) the agency has complied with the parental consent requirements under FERPA and part 300, as described in final § 300.154(d)(2)(iv)(A), before personally identifiable information is released to a State’s Medicaid agency or other public insurance program for

billing purposes and (2) before seeking to access a child’s or parent’s public benefits or insurance program for the first time to provide or pay for services required under Part B.

This written notification also must be provided annually thereafter. These changes allow public agencies to save the costs associated with obtaining written consent from parents each time access to their or their child’s public benefits or insurance is sought. We estimate that the changes to final § 300.154(d)(2)(iv) will result in net cost savings and provide an economic benefit to LEAs in many States.

Savings From Reduction in Current Requirements

Although we do not have data on the number of children who participate in both IDEA Part B and public benefits or insurance programs, a Congressional Research Service (CRS) report indicates that at least 25 percent of children receiving services under Part B of IDEA are eligible for Medicaid services (including children who are eligible for but not enrolled in Medicaid).¹ For this analysis, we assume that 20–30 percent of the 6,558,000 students served under the Part B program are also enrolled in public benefits or insurance programs for a total of 1,311,600 to 1,967,400 children. While some LEAs do not currently use public benefits or insurance to pay for services that are eligible for reimbursement, we do not know the number of eligible students who are enrolled in these LEAs. Accordingly, this analysis assumes that all LEAs seek to use public benefits or insurance for all students who are served under Part B and are eligible for public benefits or insurance. As a result, our analysis likely overestimates the number of students for which LEAs currently need parental consent to access public benefits or insurance.

Costs of Current Requirements

Under the current regulations, we assume that LEAs need to obtain consent 1.2 times per year for each eligible student for a total of 1,573,920 to 2,360,880 consent requests per year. If we assume that the consent forms are no more than 4 pages long and that it takes approximately 5–10 minutes to draft and print these forms for each consent request (forms must be tailored to the specific services and duration of services as specified in the child’s IEP), we estimate that the cost of complying with the current regulations is

¹ U.S. Congressional Research Service. Individuals with Disabilities Education Act (IDEA) and Medicaid (RL31722; Jan. 31, 2003), by Richard Apling and Elicia Herz.

\$4,363,693 to \$12,618,904 annually based on the national average hourly compensation of \$30.87. This estimate is based on the median hourly wage for an insurance claims and policy processing clerk of \$20.19, as reported in the National Compensation Survey, December 2009-January 2011 (www.bls.gov/ncs/ocs/sp/nctb1479.pdf), and the average cost to employers for benefits to State and local government employees of 34.6 percent of total hourly compensation (Table A, www.bls.gov/news.release/ecec.nr0.htm).

In most cases (50–75 percent), we assume that although not required in the regulations, public agencies seek to obtain parental consent during a child's IEP Team meeting (either at the annual meeting or following a change in the IEP). We assume that IEP Team meetings typically include four participants (the child's special education teacher or, where appropriate, related services provider; the child's regular education teacher; a public agency representative; and one parent). Assuming it takes an average of three minutes to obtain a response regarding parental consent, the additional estimated cost under the current regulations of obtaining a response during an IEP Team meeting would be \$7,754,310 to \$17,447,198 annually, based on the average hourly compensation of the participating teachers and school or public agency representative of between \$59.82 and \$69.95 and the opportunity cost to the parent, which was calculated using the Federal minimum wage. The median wages of participants, excluding the parent, were obtained from the National Compensation Survey, December 2009-January 2011 (www.bls.gov/ncs/ocs/sp/nctb1479.pdf) and 34.6 percent of total hourly compensation was used as the average cost to employers for benefits to State and local government employees (Table A, www.bls.gov/news.release/ecec.nr0.htm).

In the 25 to 50 percent of cases where a response is not obtained during an IEP Team meeting (or the agency and parents agree to make a change in the IEP without convening an IEP Team meeting as permitted under the Act and regulations), we assume that public agencies mail forms directly to parents to be completed and returned and incur additional administrative, postage, and material costs. Of the parents who receive consent forms sent via mail, we estimate that only 30–50 percent of those recipients will respond to any particular letter request, with a maximum of 3 letters sent to any particular parent for a total of 688,590

to 2,585,164 letters sent. We estimate that the cost of mailing consent forms includes \$0.45 for postage, \$0.10 for an envelope, and \$0.20 to duplicate or print each 4-page form. Each consent form returned by parents requires return postage of \$0.45 and \$0.10 for an envelope. We estimate these combined postage and materials costs are \$627,109 to \$2,129,337.² If, based on the national average hourly compensation for a secretary or administrative assistant of \$27.14, it takes approximately 10–15 minutes of administrative time for each letter sent to track the addresses of parents who have not provided a response, mail forms to parents, and process responses, and if, based on the Federal minimum wage, it takes an additional 5 minutes for the opportunity cost to parents to respond to a consent request, we estimate that the additional cost of time spent by public agencies and parents is \$3,322,734 to \$18,008,896. The estimated cost of administrative time was based on the median hourly wage of a secretary or administrative assistant of \$17.75, as reported in the, National Compensation Survey, December 2009-January 2011 (www.bls.gov/ncs/ocs/sp/nctb1479.pdf), and 34.6 percent of total hourly compensation was used as the average cost to employers for benefits to State and local government employees (Table A, www.bls.gov/news.release/ecec.nr0.htm). Based on these estimates, eliminating the parental consent requirement in current § 300.154(d)(2)(iv)(A) will result in gross savings of \$16,067,846 to \$50,204,335 annually.

Costs of Additional Requirements

The final regulations in § 300.154(d)(2)(iv) permit public agencies to access a child's or parent's public benefits or insurance if the public agency obtains written, parental consent and provides written notification to the child's parents prior to accessing the child's or parents' public benefits or insurance for the first time and provides written notification to parents annually thereafter to inform them of their rights and protections under the Act. The written consent must (a) meet the requirements of 34 CFR 99.30 and § 300.622; and (b) specify that the parent understands and agrees that the public agency may access the parent's or child's public benefits or insurance to pay for services under part 300.

² Amounts shown are the additional postage and material costs of sending forms via mail; the cost of the first form copy is not included.

We believe that initially there would be no additional cost to comply with the revised consent requirements in the final regulations for students already enrolled in Medicaid and for whom parents have already provided consent under 34 CFR 99.30 and § 300.622 and that consent meets the requirements of current § 300.154(d)(2)(iv)(A). However, at the time this consent is no longer valid because of a change in the type amount or cost of services, the public agency must obtain parental consent to seek further access to the child's or parent's public benefits or insurance to provide or pay for services under part 300. This consent must specify that the parent understands and agrees that the public agency may access the child's or parent's public benefits or insurance to pay for services under part 300. We estimate that the costs of obtaining written consent will be the same costs incurred under current IDEA requirements for obtaining consent each time the public agency seeks to access a public benefits or public insurance program.

Of the 1,311,600 to 1,967,400 children we estimate to be enrolled in Medicaid, we do not know how many in any one year are children for whom the public agency is seeking to access a public benefits or insurance program for the first time. However, we estimate for purposes of these final regulations that there are roughly 100,237 to 150,355 such children,³ leaving a total of 1,211,363 to 1,817,045 children for whom the agency would be required to obtain a one-time consent when there is a change in services. We estimate that the cost of obtaining this one-time consent under the final regulations would be \$12,366,571 to \$38,639,632. This assumes that LEAs would incur costs in obtaining the required consent in IEP Team meetings and in mailing the consent forms to parents from whom they were not able to obtain consent in such meetings.

For the remaining children for whom the public agency is seeking to access public benefits or insurance for the first time, there would be a minimal cost associated with obtaining the consent required under new § 300.154(d)(2)(iv)(B) because LEAs could meet this requirement by presenting parents with a modified FERPA and IDEA consent form (which they should already have in place for the release of the child's personally

³ Our estimate of the number of children for whom the agency would be seeking to access public benefits or insurance for the first time is based on an estimate of the number of newly identified children under IDEA using IDEA child count data for the period 2004–2010.

identifiable information to the public benefits or insurance program for billing purposes), or by presenting parents with a separate consent form that meets the requirements in new § 300.154(d)(2)(iv)(B) at the same time the agency is seeking the consent required under 34 CFR part 99 and § 300.622.

Although the specific format and content may vary by State, we estimate that it will take no more than 10 hours per State to draft a consent form that complies with these requirements. Although the parental consent requirement generally rests with LEAs, we assume States will choose to create a standard consent form in order to increase efficiency and address any applicable State laws. We estimate that the cost per State of drafting this document will be no more than \$590, for a national cost of approximately \$35,000 based on the national average hourly compensation for lawyers employed by State or local governments of \$38.46, as reported in the National Compensation Survey, December 2009–January 2011 (<http://www.bls.gov/ncs/ocs/sp/nctb1479.pdf>), and the average cost to employers for benefits to State and local government employees of 34.6 percent of total hourly compensation (Table A, www.bls.gov/news.release/ecec.nr0.htm).

We further estimate that it would take approximately 30 minutes for an administrative assistant in each of the 16,330 LEAs to obtain and modify the State's model form for use in that LEA. The total cost of preparing new FERPA and IDEA consent forms would therefore be \$222,000, based on the national average hourly compensation of \$27.14. The estimated cost of compensation was based on the median hourly wage of a secretary or administrative assistant of \$17.75, as reported in the National Compensation Survey, December 2009–January 2011 (www.bls.gov/ncs/ocs/sp/nctb1479.pdf), and the average cost to employers for benefits to State and local government employees of 34.6 percent of total hourly compensation (Table A, www.bls.gov/news.release/ecec.nr0.htm). The number of LEAs is taken from the National Center for Education Statistics Schools and Staffing Survey, "Public School District Data File," 2007–08.

The total cost of drafting FERPA and IDEA consent forms, including drafting the State model form and customizing it for use in each LEA, will be at most a one-time cost of an estimated \$257,000.

Final § 300.154(d)(2)(v) specifies that written notifications to the child's parents consistent with § 300.503(c)

include (a) A statement of the parental consent provisions in § 300.154(d)(2)(iv)(A)–(B); (b) a statement of the "no cost" provisions in § 300.154(d)(2)(i)–(d)(2)(iii); (c) a statement that the parents have the right under 34 CFR part 99 and part 300 to withdraw at any time their consent to disclosure of their child's personally identifiable information; and (d) a statement that the withdrawal of consent or refusal to provide consent under 34 CFR part 99 and part 300 to disclose personally identifiable information does not relieve the public agency of its responsibility to ensure that all required services are provided at no cost to the parents.

We do not expect the requirement for written notification to result in significant costs. While the written notification must be provided to the child's parents before the public agency may access the child's or parent's public benefits or insurance for the first time to pay for services under Part 300 and annually thereafter, the timing of the written notification is otherwise left to the discretion of public agencies. In many instances, public agencies will have an opportunity to provide this written notification, either by mail or in person, in conjunction with other required documentation or activities and will incur only the additional cost of photocopying the written notification.

Although the specific format and content may vary by State, we estimate that it will take no more than 10 hours per State to draft a written document that complies with these requirements and that the document will not exceed 4 pages in length. Although the written notification requirement generally rests with LEAs, we assume States will choose to create a standard notification in order to increase efficiency and address any applicable State laws. We estimate that the cost per State of drafting this document will be no more than \$590, for a national cost of approximately \$35,000 based on the national average hourly compensation for lawyers employed by State or local governments of \$38.46, as reported in the National Compensation Survey, December 2009–January 2011 (<http://www.bls.gov/ncs/ocs/sp/nctb1479.pdf>), and the average cost to employers for benefits to State and local government employees of 34.6 percent of total hourly compensation (Table A, www.bls.gov/news.release/ecec.nr0.htm).

Assuming all 16,330 LEAs need to prepare written notifications and that it would take approximately 30 minutes for an administrative assistant to obtain

and modify the State's standard notification for use in that LEA, the total cost of preparing written notifications will be \$222,000, based on the national average hourly compensation of \$27.14. The estimated cost of compensation was based on the median hourly wage of a secretary or administrative assistant of \$17.75, as reported in the National Compensation Survey, December 2009–January 2011 (www.bls.gov/ncs/ocs/sp/nctb1479.pdf), and the average cost to employers for benefits to State and local government employees of 34.6 percent of total hourly compensation (Table A, www.bls.gov/news.release/ecec.nr0.htm). The number of LEAs is taken from the National Center for Education Statistics Schools and Staffing Survey, "Public School District Data File," 2007–08. If the written notification is assumed to be no more than 4 pages long, then the cost of photocopying this document for the estimated 1,311,600 to 1,967,400 children who participate in both Part B and a public benefits or insurance program will be approximately \$263,000 to \$394,000 annually.

In some instances, public agencies will be unable to provide the written notification in conjunction with other mailings or in person and will need to provide that written notification by mail separately. We assume that sending written notifications by mail separately will be necessary for one-half of the eligible children and that the cost of each written notification would be \$0.55.⁴ The resulting additional cost of mailing these notifications will be an estimated \$361,000 to \$541,000. The total cost of the written annual notification requirement, including drafting the State model notification, customizing it for use in each LEA, and either copying it for distribution at the IEP Team meeting or mailing it to parents, will be an estimated \$881,000 to \$1,192,000 in the first year and \$624,000 to \$935,000 annually thereafter.

After accounting for additional parental consent and written notification costs resulting from the final regulations, the net savings will be \$2,563,275 to \$10,115,702 in the first year and \$15,443,846 to \$49,269,335 annually thereafter, assuming the costs associated with obtaining parental consent for children for whom the agency is already accessing public benefits or insurance occur in year one.

⁴ The additional cost of mailing a notification includes \$0.45 in postage, and \$0.10 for an envelope.

Paperwork Reduction Act of 1995

The Paperwork Reduction Act of 1995 does not require you to respond to a collection of information unless it displays a valid OMB control number. We display the valid OMB control numbers assigned to the collection of information in these final regulations at the end of the affected section of the regulations.

These final regulations include one information collection requirement associated with the following provisions: § 300.154(d)(2)(iv)–(v).

A description of these provisions is given below with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Collection of Information: State and Local Educational Agency Record Keeping, Notification, and Reporting Requirements under Part B of the Individuals with Disabilities Education Act (Information Collection 1820–0600). The affected section of the regulations for this information collection is final § 300.154(d)(2)(iv)–(v). The Act requires SEAs and LEAs to gather, maintain, report, and disclose various information and data, but the Act does not require this information and data to be submitted to the Department.

The final regulations in § 300.154(d)(2)(iv)–(v) permit public agencies to access a child's or parent's public benefits or insurance if the public agency provides written notification to the child's parents of their protections under the Act, obtains written consent prior to accessing the child's or parents' public benefits or insurance for the first time, and provides annual written notification to parents thereafter.

Each LEA must obtain written parental consent after providing the written notification to parents. Assuming that each SEA will develop a model consent form that its LEAs can use, and that it will take an average of about 10 hours to draft the consent form for each of the 60 grantees funded under Part B of IDEA, we estimate a total burden of 600 hours for SEAs to develop a model consent form.

We further estimate that as an uppermost bound it will take an additional 8,165 hours for LEA staff to obtain and modify an existing model consent form, based on not more than 30 minutes for each of the 16,330 LEAs. However, we would expect that most LEAs will simply use the model consent

form provided by their SEA. Therefore, we estimate the burden for the first year of implementation of this consent requirement to be not more than 8,765 hours.

Additionally, each LEA must provide a written notification to parents prior to accessing a child's or parents' public benefits or insurance for the first time and annually thereafter. Assuming that each SEA will develop a model written notification that its LEAs can use and assuming that it will take an average of about 10 hours to draft the written document for each of the 60 grantees funded under Part B of IDEA, we estimate a total burden of 600 hours for SEAs to develop a model notification.

We further estimate that as an uppermost bound it will take an additional 8,165 hours for LEA staff to obtain and modify an existing model notification, based on not more than 30 minutes for each of the 16,330 LEAs. However, we would expect that most LEAs will simply use the model notification provided by their SEA. Therefore, we estimate the burden for the first year of implementation of this notification requirement to be not more than 8,765 hours.

With the addition of the burden to SEAs and LEAs associated with final § 300.154(d)(2)(iv)–(v), the total annual record keeping and notification burden for this collection of information is estimated to be approximately 490,181 hours for the 104,349 separate responses from SEAs and LEAs.

Intergovernmental Review

This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Assessment of Educational Impact

In the NPRM we requested comments on whether the proposed regulations would require transmission of information that any other agency or authority of the United States gathers or makes available.

Based on the response to the NPRM and on our review, we have determined that these final regulations do not require transmission of information that any other agency or authority of the United States gathers or makes available.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: www.gpo.gov/fdsys. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

You may also view this document in text [or PDF] at the following site: idea.ed.gov.

(Catalog of Federal Domestic Assistance Number 84.181)

List of Subjects in 34 CFR Part 300

Administrative practice and procedure, Education of individuals with disabilities, Elementary and secondary education, Grant programs—education, Privacy, Private schools, Reporting and recordkeeping requirements.

Dated: February 8, 2013.

Arne Duncan,
Secretary of Education.

For the reasons discussed in the preamble, the Secretary amends 34 CFR chapter III as follows:

PART 300—ASSISTANCE TO STATES FOR THE EDUCATION OF CHILDREN WITH DISABILITIES

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 20 U.S.C. 1221e–3, 1406, 1411–1419, unless otherwise noted.

■ 2. Section 300.154 is amended by:
■ a. Revising paragraph (d)(2)(iv).
■ b. Adding new paragraph (d)(2)(v).

The revision and addition read as follows:

§ 300.154 Methods of ensuring services.

* * * * *

(d) * * *

(2) * * *

(iv) Prior to accessing a child's or parent's public benefits or insurance for the first time, and after providing notification to the child's parents consistent with paragraph (d)(2)(v) of this section, must obtain written, parental consent that—

(A) Meets the requirements of § 99.30 of this title and § 300.622, which consent must specify the personally identifiable information that may be disclosed (e.g., records or information about the services that may be provided to a particular child), the purpose of the disclosure (e.g., billing for services under part 300), and the agency to which the disclosure may be made (e.g., the State's public benefits or insurance program (e.g., Medicaid)); and

(B) Specifies that the parent understands and agrees that the public agency may access the parent's or child's public benefits or insurance to pay for services under part 300.

(v) Prior to accessing a child's or parent's public benefits or insurance for the first time, and annually thereafter, must provide written notification, consistent with § 300.503(c), to the child's parents, that includes—

(A) A statement of the parental consent provisions in paragraphs (d)(2)(iv)(A) and (B) of this section;

(B) A statement of the "no cost" provisions in paragraphs (d)(2)(i) through (iii) of this section;

(C) A statement that the parents have the right under 34 CFR part 99 and part 300 to withdraw their consent to disclosure of their child's personally identifiable information to the agency responsible for the administration of the State's public benefits or insurance program (e.g., Medicaid) at any time; and

(D) A statement that the withdrawal of consent or refusal to provide consent under 34 CFR part 99 and part 300 to disclose personally identifiable information to the agency responsible for the administration of the State's public benefits or insurance program (e.g., Medicaid) does not relieve the public agency of its responsibility to ensure that all required services are provided at no cost to the parents.

* * * * *

[FR Doc. 2013-03443 Filed 2-13-13; 8:45 am]

BILLING CODE 4000-01-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 26**

[EPA-HQ-OPP-2010-0785; FRL-9353-4]

RIN 2070-AJ76

Protections for Subjects in Human Research Involving Pesticides**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: EPA is finalizing narrowly tailored amendments to the portions of its rules for the protection of human subjects of research applying to third parties who conduct or support research with pesticides involving intentional exposure of human subjects and to persons who submit the results of human research with pesticides to EPA. The amendments broaden the applicability of the rules to cover human testing with pesticides submitted to EPA under any regulatory statute it administers. The amendments also disallow participation in third-party pesticide studies by subjects who cannot consent for themselves. Finally, the amendments identify specific considerations to be addressed in EPA science and ethics reviews of proposed and completed human research with pesticides, drawn from the recommendations of the National Academy of Sciences (NAS). The amendments make no changes to the current Federal Policy for the Protection of Human Subjects (the "Common Rule"), which governs research with human subjects conducted or supported by EPA and many other Federal departments and agencies.

DATES: This rule is effective April 15, 2013.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2010-0785, is available at <http://www.regulations.gov> or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in the EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Kelly Sherman, Immediate Office of the

Director (7501P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-8401; fax number: (703) 308-4776; email address: sherman.kelly@epa.gov.

SUPPLEMENTARY INFORMATION:**I. Executive Summary***A. Does this action apply to me?*

You may be potentially affected by this action if you conduct or sponsor research that may be submitted to EPA and which involves intentional exposure of human subjects. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document might apply to them. Although EPA has in the past received such third-party research from pesticide registrants, other entities could submit such information to EPA.

- Pesticide and other Agricultural Chemical Manufacturing (NAICS code 325320) who sponsor or conduct human research with pesticides.
- Other entities (NAICS code 541710) that sponsor or conduct human research with pesticides, and Institutional Review Boards (IRBs) who review human research with pesticides to ensure it meets applicable standards of ethical conduct. Under these new provisions, EPA must consider the ethical aspects and scientific validity and reliability of research in a manner that is consistent with the requirements of the Common Rule as codified in 40 CFR part 26, subpart A. The "Common Rule" is the name generally used to refer to the Federal Policy for the Protection of Human Subjects, which governs research with human subjects conducted or supported by EPA and many other Federal departments and agencies. EPA's codification of the Common Rule appears as subpart A in 40 CFR part 26.

B. What action is the agency taking?

The amendments contained in this final rule change the 2006 rule, published in the **Federal Register** issue of February 6, 2006 (71 FR 6138) (FRL-7759-8), subsequently amended in the **Federal Register** issue of June 23, 2006 (71 FR 36171) (FRL-8071-6), and codified at 40 CFR part 26, in the following substantive respects:

- By broadening the applicability of 40 CFR part 26, subparts K, L, M, and Q, so these subparts would apply not only to research submitted to or considered by EPA under the pesticide