the unique language and communication needs of deaf and hard of hearing newborns, infants, toddlers, and children.''

Subsec. (a)(3). Pub. L. 111–337, § 2(2)(C), added par. (3).

Subsec. (b)(1)(A). Pub. L. 111–337, § 2(3), substituted ''hearing loss screening, evaluation, diagnosis, and intervention programs'' for ''hearing loss screening, evaluation, and intervention programs''.

Subsec. (c)(2), (3). Pub. L. 111–337, § 2(4), substituted ''hearing screening, evaluation, diagnosis, and intervention programs'' for ''hearing screening, evaluation and intervention programs''.

Subsec. (e)(3). Pub. L. 111–337, § 2(5)(A), substituted ''ensuring that families of the child are provided comprehensive, consumer-oriented information about the full range of family support, training, information services, and language and communication options and are given the opportunity to consider and obtain the full range of such appropriate services, educational and program placements, and other options for their child from highly qualified providers.'' for ''ensuring that families of the child are provided comprehensive, consumer-oriented information about the full range of family support, training, information services, communication options and are given the opportunity to consider the full range of educational and program placements and options for their child.''

Subsec. (e)(6). Pub. L. 111–337, § 2(5)(B), struck out '', after rescreening,'' after ''infants who''.

Subsec. (f). Pub. L. 111–337, § 2(6), substituted ''fiscal years 2011 through 2015'' for ''fiscal year 2002'' in pars. (1) to (3).

JAMES T. WALSH UNIVERSAL NEWBORN HEARING SCREENING PROGRAM

Pub. L. 111–8, div. F, title II, § 224, Mar. 11, 2009, 123 Stat. 784, provided that: ''Hereafter, the activities authorized under section 399M of the Public Health Service Act [42 U.S.C. 280g–1] shall be known as the 'James T. Walsh Universal Newborn Hearing Screening Program.'''

PURPOSES

Pub. L. 106–310, div. A, title VII, § 701, Oct. 17, 2000, 114 Stat. 1120, provided that: ''The purposes of this title [enacting this section] are to clarify the authority within the Public Health Service Act [42 U.S.C. 201 et seq.] to authorize statewide newborn and infant hearing screening, evaluation and intervention programs and systems, technical assistance, a national applied research program, and interagency and private sector collaboration for policy development, in order to assist the States in making progress toward the following goals:

''(1) All babies born in hospitals in the United States and its territories should have a hearing screening before leaving the birthing facility. Babies born in other countries and residing in the United States via immigration or adoption should have a hearing screening as early as possible.

''(2) All babies who are not born in hospitals in the United States and its territories should have a hearing screening within the first 3 months of life.

''(3) Appropriate audiologic and medical evaluations should be conducted by 3 months for all newborns and infants suspected of having hearing loss to allow appropriate referral and provisions for audiologic rehabilitation, medical and early intervention before the age of 6 months.

''(4) All newborn and infant hearing screening programs and systems should include a component for audiologic rehabilitation, medical and early intervention options that ensures linkage to any new and existing state-wide systems of intervention and rehabilitative services for newborns and infants with hearing loss.

''(5) Public policy in regard to newborn and infant hearing screening and intervention should be based on applied research and the recognition that newborns, infants, toddlers, and children who are deaf or hard-of-hearing have unique language, learning, and communication needs, and should be the result of consultation with pertinent public and private sectors.''

§ 280g–2. Childhood malignancies

(a) In general

The Secretary, acting as appropriate through the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall study environmental and other risk factors for childhood cancers (including skeletal malignancies, leukemias, malignant tumors of the central nervous system, lymphomas, soft tissue sarcomas, and other malignant neoplasms) and carry out projects to improve outcomes among children with childhood cancers and resultant secondary conditions, including limb loss, anemia, rehabilitation, and palliative care. Such projects shall be carried out by the Secretary directly and through awards of grants or contracts.

(b) Certain activities

Activities under subsection (a) include—

(1) the expansion of current demographic data collection and population surveillance efforts to include childhood cancers nationally;

(2) the development of a uniform reporting system under which treating physicians, hospitals, clinics, and States report the diagnosis of childhood cancers, including relevant associated epidemiological data; and

(3) support for the National Limb Loss Information Center to address, in part, the primary and secondary needs of persons who experience childhood cancers in order to prevent or minimize the disabling nature of these cancers.

(c) Coordination of activities

The Secretary shall assure that activities under this section are coordinated as appropriate with other agencies of the Public Health Service that carry out activities focused on childhood cancers and limb loss.

(d) Definition

For purposes of this section, the term ''childhood cancer'' refers to a spectrum of different malignancies that vary by histology, site of disease, origin, race, sex, and age. The Secretary may for purposes of this section revise the definition of such term to the extent determined by the Secretary to be appropriate.

(e) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, § 399N, as added Pub. L. 106–310, div. A, title XI, § 1101, Oct. 17, 2000, 114 Stat. 1131.)

§ 280g–3. Prescription drug monitoring program

(a) Program

(1) In general

Each fiscal year, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, in coordination

with the heads of other departments and agencies as appropriate, shall support States or localities for the purpose of improving the efficiency and use of PDMPs, including—

(A) establishment and implementation of a PDMP;

(B) maintenance of a PDMP;

(C) improvements to a PDMP by—

(i) enhancing functional components to work toward—

(I) universal use of PDMPs among providers and their delegates, to the extent that State laws allow;

(II) more timely inclusion of data within a PDMP;

(III) active management of the PDMP, in part by sending proactive or unsolicited reports to providers to inform prescribing; and

(IV) ensuring the highest level of ease in use of and access to PDMPs by providers and their delegates, to the extent that State laws allow;

(ii) in consultation with the Office of the National Coordinator for Health Information Technology, improving the intrastate interoperability of PDMPs by—

(I) making PDMPs more actionable by integrating PDMPs within electronic health records and health information technology infrastructure; and

(II) linking PDMP data to other data systems within the State, including—

(aa) the data of pharmacy benefit managers, medical examiners and coroners, and the State's Medicaid program;

(bb) worker's compensation data; and

(cc) prescribing data of providers of the Department of Veterans Affairs and the Indian Health Service within the State;

(iii) in consultation with the Office of the National Coordinator for Health Information Technology, improving the interstate interoperability of PDMPs through—

(I) sharing of dispensing data in near-real time across State lines; and

(II) integration of automated queries for multistate PDMP data and analytics into clinical workflow to improve the use of such data and analytics by practitioners and dispensers; or

(iv) improving the ability to include treatment availability resources and referral capabilities within the PDMP.

(2) Legislation

As a condition on the receipt of support under this section, the Secretary shall require a State or locality to demonstrate that it has enacted legislation or regulations—

(A) to provide for the implementation of the PDMP; and

(B) to permit the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained by the PDMP.

(b) PDMP strategies

The Secretary shall encourage a State or locality, in establishing, improving, or maintaining a PDMP, to implement strategies that improve—

(1) the reporting of dispensing in the State or locality of a controlled substance to an ultimate user so the reporting occurs not later than 24 hours after the dispensing event;

(2) the consultation of the PDMP by each prescribing practitioner, or their designee, in the State or locality before initiating treatment with a controlled substance, or any substance as required by the State to be reported to the PDMP, and over the course of ongoing treatment for each prescribing event;

(3) the consultation of the PDMP before dispensing a controlled substance, or any substance as required by the State to be reported to the PDMP;

(4) the proactive notification to a practitioner when patterns indicative of controlled substance misuse by a patient, including opioid misuse, are detected;

(5) the availability of data in the PDMP to other States, as allowable under State law; and

(6) the availability of nonidentifiable information to the Centers for Disease Control and Prevention for surveillance, epidemiology, statistical research, or educational purposes.

(c) Drug misuse and abuse

In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving support under this section—

(1) shall establish a program to notify practitioners and dispensers of information that will help to identify and prevent the unlawful diversion or misuse of controlled substances;

(2) may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines that information in the PDMP maintained by the State indicates an unlawful diversion or abuse of a controlled substance;

(3) may conduct analyses of controlled substance program data for purposes of providing appropriate State agencies with aggregate reports based on such analyses in as close to real-time as practicable, regarding prescription patterns flagged as potentially presenting a risk of misuse, abuse, addiction, overdose, and other aggregate information, as appropriate and in compliance with applicable Federal and State laws and provided that such reports shall not include protected health information; and

(4) may access information about prescriptions, such as claims data, to ensure that such prescribing and dispensing history is updated in as close to real-time as practicable, in compliance with applicable Federal and State laws and provided that such information shall not include protected health information.

(d) Evaluation and reporting

As a condition on receipt of support under this section, the State shall report on interoperability with PDMPs of other States and Federal agencies, where appropriate, intrastate interoperability with health information technology systems such as electronic health records, health information exchanges, and e-pre-

scribing, where appropriate, and whether or not the State provides automatic, up-to-date, or daily information about a patient when a practitioner (or the designee of a practitioner, where permitted) requests information about such patient.

(e) Evaluation and reporting

A State receiving support under this section shall provide the Secretary with aggregate nonidentifiable information, as permitted by State law, to enable the Secretary—

(1) to evaluate the success of the State's program in achieving the purpose described in subsection (a); or

(2) to prepare and submit to the Congress the report required by subsection (i)(2).

(f) Education and access to the monitoring system

A State receiving support under this section shall take steps to—

(1) facilitate prescribers and dispensers, and their delegates, as permitted by State law, to use the PDMP, to the extent practicable; and

(2) educate prescribers and dispensers, and their delegates on the benefits of the use of PDMPs.

(g) Electronic format

The Secretary may issue guidelines specifying a uniform electronic format for the reporting, sharing, and disclosure of information pursuant to PDMPs. To the extent possible, such guidelines shall be consistent with standards recognized by the Office of the National Coordinator for Health Information Technology.

(h) Rules of construction

(1) Functions otherwise authorized by law

Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.

(2) Additional privacy protections

Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

(3) Federal privacy requirements

Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and section 290dd–2 of this title.

(4) No Federal private cause of action

Nothing in this section shall be construed to create a Federal private cause of action.

(i) Progress report

Not later than 3 years after October 24, 2018, the Secretary shall—

(1) complete a study that—

(A) determines the progress of grantees in establishing and implementing PDMPs consistent with this section;

(B) provides an analysis of the extent to which the operation of PDMPs has—

(i) reduced inappropriate use, abuse, diversion of, and overdose with, controlled substances;

(ii) established or strengthened initiatives to ensure linkages to substance use disorder treatment services; or

(iii) affected patient access to appropriate care in States operating PDMPs;

(C) determine[1] the progress of grantees in achieving interstate interoperability and intrastate interoperability of PDMPs, including an assessment of technical, legal, and financial barriers to such progress and recommendations for addressing these barriers;

(D) determines the progress of grantees in implementing near real-time electronic PDMPs;

(E) provides an analysis of the privacy protections in place for the information reported to the PDMP in each State or locality receiving support under this section and any recommendations of the Secretary for additional Federal or State requirements for protection of this information;

(F) determines the progress of States or localities in implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in PDMPs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

(G) evaluates the penalties that States or localities have enacted for the unauthorized use and disclosure of information maintained in PDMPs, and the criteria used by the Secretary to determine whether such penalties qualify as appropriate for purposes of subsection (a)(2); and

(2) submit a report to the Congress on the results of the study.

(j) Advisory Council

(1) Establishment

A State or locality may establish an advisory council to assist in the establishment, improvement, or maintenance of a PDMP consistent with this section.

(2) Limitation

A State or locality may not use Federal funds for the operations of an advisory council to assist in the establishment, improvement, or maintenance of a PDMP.

(3) Sense of Congress

It is the sense of the Congress that, in establishing an advisory council to assist in the establishment, improvement, or maintenance of a PDMP, a State or locality should consult with appropriate professional boards and other interested parties.

(k) Definitions

For purposes of this section:

(1) The term ''controlled substance'' means a controlled substance (as defined in section 802 of title 21) in schedule II, III, or IV of section 812 of such title.

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[1] So in original. Probably should be ''determines''.

(2) The term ''dispense'' means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

(3) The term ''dispenser'' means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.

(4) The term ''interstate interoperability'' with respect to a PDMP means the ability of the PDMP to electronically share reported information with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

(5) The term ''intrastate interoperability'' with respect to a PDMP means the integration of PDMP data within electronic health records and health information technology infrastructure or linking of a PDMP to other data systems within the State, including the State's Medicaid program, workers' compensation programs, and medical examiners or coroners.

(6) The term ''nonidentifiable information'' means information that does not identify a practitioner, dispenser, or an ultimate user and with respect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.

(7) The term ''PDMP'' means a prescription drug monitoring program that is State-controlled.

(8) The term ''practitioner'' means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which the individual practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(9) The term ''State'' means each of the 50 States, the District of Columbia, and any commonwealth or territory of the United States.

(10) The term ''ultimate user'' means a person who has obtained from a dispenser, and who possesses, a controlled substance for the person's own use, for the use of a member of the person's household, or for the use of an animal owned by the person or by a member of the person's household.

(11) The term ''clinical workflow'' means the integration of automated queries for prescription drug monitoring programs data and analytics into health information technologies such as electronic health record systems, health information exchanges, and/or pharmacy dispensing software systems, thus streamlining provider access through automated queries.

(July 1, 1944, ch. 373, title III, § 399O, as added Pub. L. 109–60, § 3, Aug. 11, 2005, 119 Stat. 1979; amended Pub. L. 114–198, title I, § 109(b), July 22, 2016, 130 Stat. 706; Pub. L. 115–271, title VII, § 7162, Oct. 24, 2018, 132 Stat. 4062.)

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (h)(3), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

CODIFICATION

Another section 399O of act July 1, 1944, was renumbered section 399P and is classified to section 280g–4 of this title.

AMENDMENTS

2018—Pub. L. 115–271 amended section generally. Prior to amendment, section related to grants for State controlled substance monitoring programs.

2016—Subsec. (a)(1). Pub. L. 114–198, § 109(b)(1)(A), inserted '', in consultation with the Administrator of the Substance Abuse and Mental Health Services Administration and Director of the Centers for Disease Control and Prevention,'' after ''the Secretary'' in introductory provisions.

Subsec. (a)(1)(C). Pub. L. 114–198, § 109(b)(1)(B)–(D), added subpar. (C).

Subsec. (b). Pub. L. 114–198, § 109(b)(2), amended subsec. (b) generally. Prior to amendment, text read as follows: ''Prior to awarding a grant under this section, and not later than 6 months after the date on which funds are first appropriated to carry out this section, after seeking consultation with States and other interested parties, the Secretary shall, after publishing in the Federal Register proposed minimum requirements and receiving public comments, establish minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A) of this section.''

Subsec. (c)(1)(A)(iv). Pub. L. 114–198, § 109(b)(9), substituted ''subsection (i)'' for ''subsection (h)''.

Subsec. (c)(1)(B). Pub. L. 114–198, § 109(b)(3)(A)(i), substituted ''(a)(1)(B) or (a)(1)(C)'' for ''(a)(1)(B)'' in introductory provisions.

Subsec. (c)(1)(B)(i). Pub. L. 114–198, § 109(b)(3)(A)(ii), substituted ''program to be improved or maintained'' for ''program to be improved''.

Subsec. (c)(1)(B)(iii). Pub. L. 114–198, § 109(b)(3)(A)(iv), added cl. (iii). Former cl. (iii) redesignated (iv).

Subsec. (c)(1)(B)(iv). Pub. L. 114–198, § 109(b)(3)(A)(iii), (v), redesignated cl. (iii) as (iv) and substituted ''and at least one health information technology system such as electronic health records, health information exchanges, or e-prescribing systems;'' for ''; and''. Former cl. (iv) redesignated (v).

Subsec. (c)(1)(B)(v). Pub. L. 114–198, § 109(b)(3)(A)(iii), (vi), redesignated cl. (iv) as (v) and substituted ''public health or safety in such State; and'' for ''public health in such State.''

Subsec. (c)(1)(B)(vi). Pub. L. 114–198, § 109(b)(3)(A)(vii), added cl. (vi).

Subsec. (c)(3). Pub. L. 114–198, § 109(b)(3)(B), designated existing provisions as subpar. (A) and inserted heading, inserted before period at end ''and include timelines for full implementation of such interoperability. The State shall also describe the manner in which it will achieve interoperability between its monitoring program and health information technology systems, as allowable under State law, and include timelines for the implementation of such interoperability'', and added subpar. (B).

Subsec. (c)(5). Pub. L. 114–198, § 109(b)(3)(C), substituted ''establish, improve, or maintain'' for ''implement or improve'' and inserted at end ''The Secretary shall redistribute any funds that are so returned among the remaining grantees under this section in accordance with the formula described in subsection (a)(2)(B).''

Subsec. (d). Pub. L. 114–198, § 109(b)(4)(A), in introductory provisions, substituted ''In establishing, improving, or maintaining a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under

subparagraph (B) or (C) of subsection (a)(1)'' for ''In implementing or improving a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subsection (a)(1)(B)'' and ''public health or safety'' for ''public health''.

Subsec. (d)(4). Pub. L. 114–198, §109(b)(9), substituted ''subsection (i)'' for ''subsection (h)''.

Subsec. (d)(5). Pub. L. 114–198, §109(b)(4)(B), added par. (5).

Subsecs. (e), (f)(1). Pub. L. 114–198, §109(b)(5), substituted ''establishing, improving, or maintaining'' for ''implementing or improving'' in introductory provisions.

Subsec. (f)(1)(B). Pub. L. 114–198, §109(b)(6)(A)(i), substituted ''misuse of a controlled substance included in schedule II, III, or IV of section 812(c) of title 21'' for ''misuse of a schedule II, III, or IV substance''.

Subsec. (f)(1)(D). Pub. L. 114–198, §109(b)(6)(A)(ii), inserted ''a State substance abuse agency,'' after ''State health department,'' and substituted ''such department, program, agency, or administration'' for ''such department, program, or administration'' in two places.

Subsec. (f)(3), (4). Pub. L. 114–198, §109(b)(6)(B), added pars. (3) and (4).

Subsec. (g). Pub. L. 114–198, §109(b)(5), substituted ''establishing, improving, or maintaining'' for ''implementing or improving'' in introductory provisions.

Subsecs. (h) to (j). Pub. L. 114–198, §109(b)(8), (10), added subsec. (h) and redesignated former subsecs. (h) and (i) as (i) and (j), respectively. Former subsec. (j) redesignated (k).

Subsec. (k). Pub. L. 114–198, §109(b)(7), (8), redesignated subsec. (j) as (k) and struck out former subsec. (k). Prior to amendment, text of subsec. (k) read as follows: ''Beginning 3 years after the date on which funds are first appropriated to carry out this section, the Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) and for which only States are eligible to apply, shall give preference to any State with an application approved under this section. The Secretary shall have the discretion to apply such preference to States with existing controlled substance monitoring programs that meet minimum requirements under this section or to States that put forth a good faith effort to meet those requirements (as determined by the Secretary).''

Subsec. (k)(2)(A)(ii). Pub. L. 114–198, §109(b)(11)(A), substituted '', established or strengthened initiatives to ensure linkages to substance use disorder services, or affected'' for ''or affected''.

Subsec. (k)(2)(A)(iii). Pub. L. 114–198, §109(b)(11)(B), substituted ''and between controlled substance monitoring programs and health information technology systems, including an assessment'' for ''including an assessment''.

Subsec. (*l*)(1). Pub. L. 114–198, §109(b)(12), substituted ''establishment, improvement, or maintenance'' for ''establishment, implementation, or improvement''.

Subsec. (m)(8). Pub. L. 114–198, §109(b)(13), substituted '', the District of Columbia, and any commonwealth or territory of the United States'' for ''and the District of Columbia''.

Subsec. (n). Pub. L. 114–198, §109(b)(14), amended subsec. (n) generally. Prior to amendment, subsec. (n) authorized appropriations for fiscal years 2006 to 2010.

PURPOSE

Pub. L. 109–60, §2, Aug. 11, 2005, 119 Stat. 1979, as amended by Pub. L. 114–198, title I, §109(a), July 22, 2016, 130 Stat. 706, provided that: ''It is the purpose of this Act [enacting this section and provisions set out as a note under section 201 of this title] to—

''(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and

''(2) establish, based on the experiences of existing State controlled substance monitoring programs, a set of best practices to guide the establishment of new State programs and the improvement of existing programs.''

§ 280g–4. Grants to strengthen the healthcare system's response to domestic violence, dating violence, sexual assault, and stalking

(a) In general

The Secretary shall award grants for—

(1) the development or enhancement and implementation of interdisciplinary training for health professionals, public health staff, and allied health professionals;

(2) the development or enhancement and implementation of education programs for medical, nursing, dental, and other health profession students and residents to prevent and respond to domestic violence, dating violence, sexual assault, and stalking; and

(3) the development or enhancement and implementation of comprehensive statewide strategies to improve the response of clinics, public health facilities, hospitals, and other health settings (including behavioral and mental health programs) to domestic violence, dating violence, sexual assault, and stalking.

(b) Use of funds

(1) Required uses

Amounts provided under a grant under this section shall be used to—

(A) fund interdisciplinary training and education programs under paragraphs (1) and (2) of subsection (a) that—

(i) are designed to train medical, psychology, dental, social work, nursing, and other health profession students, interns, residents, fellows, or current health care providers to identify and provide health care services (including mental or behavioral health care services and referrals to appropriate community services) to individuals who are or who have been victims of domestic violence, dating violence, sexual assault, or stalking; and

(ii) plan and develop culturally competent clinical training components for integration into approved internship, residency, and fellowship training or continuing medical or other health education training that address physical, mental, and behavioral health issues, including protective factors, related to domestic violence, dating violence, sexual assault, stalking, and other forms of violence and abuse, focus on reducing health disparities and preventing violence and abuse, and include the primacy of victim safety and confidentiality;

(B) design and implement comprehensive strategies to improve the response of the health care system to domestic or sexual violence in clinical and public health settings, hospitals, clinics, and other health settings (including behavioral and mental health), under subsection (a)(3) through—