

21st Century Cures Legislative Text

ASP for Home Infusion Drugs

SEC. 5004. REDUCING OVERPAYMENTS OF INFUSION DRUGS.

(a) Treatment of Infusion Drugs Furnished Through Durable Medical Equipment.--Section 1842(o)(1) of the Social Security Act (42 U.S.C. 1395u(o)(1)) is amended--

(1) in subparagraph (C), by inserting ``(and including a drug or biological described in subparagraph (D)(i) furnished on or after January 1, 2017)'' after ``2005''; and

(2) in subparagraph (D)--

(A) by striking ``infusion drugs'' and inserting ``infusion drugs or biologicals'' each place it appears; and

(B) in clause (i)--

(i) by striking ``2004'' and inserting ``2004, and before January 1, 2017''; and

(ii) by striking ``for such drug''.

(b) Noninclusion of DME Infusion Drugs Under DME Competitive Acquisition Programs.--

(1) In general.--Section 1847(a)(2)(A) of the Social Security Act (42 U.S.C. 1395w-3(a)(2)(A)) is amended--

(A) by striking ``and excluding'' and inserting ``, excluding''; and

(B) by inserting before the period at the end the following: ``, and excluding drugs and biologicals described in section 1842(o)(1)(D)''.

(2) Conforming amendment.--Section 1842(o)(1)(D)(ii) of the Social Security Act (42 U.S.C. 1395u(o)(1)(D)(ii)) is amended by striking ``2007'' and inserting ``2007, and before the date of the enactment of the 21st Century Cures Act.''.

Home Infusion Services Reimbursement

SEC. 5012. MEDICARE COVERAGE OF HOME INFUSION THERAPY.

(a) In General.--Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended--

(1) in subsection (s)(2)--

(A) by striking ``and'' at the end of subparagraph (EE);

(B) by inserting ``and'' at the end of subparagraph (FF);

and

(C) by inserting at the end the following new subparagraph:

``(GG) home infusion therapy (as defined in subsection (iii)(1));''; and

(2) by adding at the end the following new subsection:

``(iii) Home Infusion Therapy.--(1) The term `home infusion therapy' means the items and services described in paragraph (2) furnished by a qualified home infusion therapy supplier (as defined in paragraph (3)(D)) which are furnished in the individual's home (as defined in paragraph (3)(B)) to an individual--

``(A) who is under the care of an applicable provider (as defined in paragraph (3)(A)); and

``(B) with respect to whom a plan prescribing the type, amount, and duration of infusion therapy services that are to be furnished such individual has been established by a physician (as defined in

subsection (r)(1)) and is periodically reviewed by a physician (as so defined) in coordination with the furnishing of home infusion drugs (as defined in paragraph (3)(C)) under part B.

``(2) The items and services described in this paragraph are the following:

``(A) Professional services, including nursing services, furnished in accordance with the plan.

``(B) Training and education (not otherwise paid for as durable medical equipment (as defined in subsection (n))), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier.

``(3) For purposes of this subsection:

``(A) The term `applicable provider' means--

``(i) a physician;

``(ii) a nurse practitioner; and

``(iii) a physician assistant.

``(B) The term `home' means a place of residence used as the home of an individual (as defined for purposes of subsection (n)).

``(C) The term `home infusion drug' means a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in subsection (n)). Such term does not include the following:

``(i) Insulin pump systems.

``(ii) A self-administered drug or biological on a self-administered drug exclusion list.

``(D)(i) The term `qualified home infusion therapy supplier' means a pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider or services or supplier furnishes items or services and that--

``(I) furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;

``(II) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis;

``(III) is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5); and

``(IV) meets such other requirements as the Secretary determines appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under part C and in the private sector.

``(ii) A qualified home infusion therapy supplier may subcontract with a pharmacy, physician, provider of services, or supplier to meet the requirements of this subparagraph.''.

(b) Payment and Related Requirements for Home Infusion Therapy.-- Section 1834 of the Social Security Act (42 U.S.C. 1395m), as amended by section 4011, is further amended by adding at the end the following new subsection:

``(u) Payment and Related Requirements for Home Infusion Therapy.--

``(1) Payment.--

``(A) Single payment.--

``(i) In general.--Subject to clause (iii) and subparagraphs (B) and (C), the Secretary shall implement a payment system under which a single payment is made under this title to a qualified home infusion therapy supplier for items and services described in subparagraphs (A) and (B) of section 1861(iii)(2)) furnished by a qualified home infusion therapy supplier (as defined in section 1861(iii)(3)(D)) in coordination with the furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C)) under this part.

``(ii) Unit of single payment.--A unit of single payment under the payment system implemented under this subparagraph is for each infusion drug administration calendar day in the individual's home. The Secretary shall, as appropriate, establish single payment amounts for types of infusion therapy, including to take into account variation in utilization of nursing services by therapy type.

``(iii) Limitation.--The single payment amount determined under this subparagraph after application of subparagraph (B) and paragraph (3) shall not exceed the amount determined under the fee schedule under section 1848 for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day.

``(B) Required adjustments.--The Secretary shall adjust the single payment amount determined under subparagraph (A) for home infusion therapy services under section 1861(iii)(1) to reflect other factors such as--

``(i) a geographic wage index and other costs that may vary by region; and

``(ii) patient acuity and complexity of drug administration.

``(C) Discretionary adjustments.--

``(i) In general.--Subject to clause (ii), the Secretary may adjust the single payment amount determined under subparagraph (A) (after application of subparagraph (B)) to reflect outlier situations and other factors as the Secretary determines appropriate.

``(ii) Requirement of budget neutrality.--Any adjustment under this subparagraph shall be made in a

budget neutral manner.

((2) Considerations.--In developing the payment system under this subsection, the Secretary may consider the costs of furnishing infusion therapy in the home, consult with home infusion therapy suppliers, consider payment amounts for similar items and services under this part and part A, and consider payment amounts established by Medicare Advantage plans under part C and in the private insurance market for home infusion therapy (including average per treatment day payment amounts by type of home infusion therapy).

((3) Annual updates.--

((A) In general.--Subject to subparagraph (B), the Secretary shall update the single payment amount under this subsection from year to year beginning in 2022 by increasing the single payment amount from the prior year by the percentage increase in the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year.

((B) Adjustment.--For each year, the Secretary shall reduce the percentage increase described in subparagraph (A) by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in a percentage being less than 0.0 for a year, and may result in payment being less than such payment rates for the preceding year.

((4) Authority to apply prior authorization.--The Secretary may, as determined appropriate by the Secretary, apply prior authorization for home infusion therapy services under section 1861(iii)(1).

((5) Accreditation of qualified home infusion therapy suppliers.--

((A) Factors for designation of accreditation organizations.--The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

((i) The ability of the organization to conduct timely reviews of accreditation applications.

((ii) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D)).

((iii) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

((iv) Such other factors as the Secretary determines appropriate.

((B) Designation.--Not later than January 1, 2021, the Secretary shall designate organizations to accredit suppliers furnishing home infusion therapy. The list of accreditation

organizations so designated may be modified pursuant to subparagraph (C).

``(C) Review and modification of list of accreditation organizations.--

``(i) In general.--The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

``(ii) Special rule for accreditations done prior to removal from list of designated accreditation organizations.--In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

``(D) Rule for accreditations made prior to designation.--In the case of a supplier that is accredited before January 1, 2021, by an accreditation organization designated by the Secretary under subparagraph (B) as of January 1, 2019, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2023, for the remaining period such accreditation is in effect.

``(6) Notification of infusion therapy options available prior to furnishing home infusion therapy.--Prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan described in section 1861(iii)(1) for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part.''.

(c) Conforming Amendments.--

(1) Payment reference.--Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)) is amended--

(A) by striking ``and'' before ``(AA)''; and

(B) by inserting before the semicolon at the end the following: ``, and (BB) with respect to home infusion therapy, the amount paid shall be an amount equal to 80 percent of the lesser of the actual charge for the services or the amount determined under section 1834(u)''.

(2) Direct payment.--The first sentence of section 1842(b)(6) of the Social Security Act (42 U.S.C. 1395u(b)(6)) is amended--

(A) by striking ``and'' before ``(H)''; and

(B) by inserting before the period at the end the following: ``, and (I) in the case of home infusion therapy,

payment shall be made to the qualified home infusion therapy supplier''.

(3) Exclusion from home health services.--Section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)) is amended, in the first sentence, by inserting the following before the period at the end: ``and home infusion therapy (as defined in subsection (iii)(i))''.

(d) Effective Date.--The amendments made by this section shall apply to items and services furnished on or after January 1, 2021.