

**SENATE
STATE OF MINNESOTA
NINETY-SECOND SESSION**

S.F. No. 3613

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DATE	D-PG	OFFICIAL STATUS
03/02/2022	5176	Introduction and first reading
		Referred to Health and Human Services Finance and Policy
04/04/2022	6186	Comm report: To pass and re-referred to Finance

1.1 A bill for an act

1.2 relating to human services; establishing pediatric home-based enteral nutrition

1.3 services as a covered service under medical assistance; amending Minnesota

1.4 Statutes 2020, sections 256B.0625, subdivision 32, by adding a subdivision;

1.5 256B.0651, subdivisions 1, 2; 256B.0652, subdivisions 2, 11, by adding a

1.6 subdivision; 256B.766; Minnesota Statutes 2021 Supplement, section 256B.0625,

1.7 subdivision 31; proposing coding for new law in Minnesota Statutes, chapter 256B.

1.8 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

1.9 Section 1. Minnesota Statutes 2021 Supplement, section 256B.0625, subdivision 31, is

1.10 amended to read:

1.11 Subd. 31. **Medical supplies and equipment.** (a) Medical assistance covers medical

1.12 supplies and equipment. Separate payment outside of the facility's payment rate shall be

1.13 made for wheelchairs and wheelchair accessories for recipients who are residents of

1.14 intermediate care facilities for the developmentally disabled. Reimbursement for wheelchairs

1.15 and wheelchair accessories for ICF/DD recipients shall be subject to the same conditions

1.16 and limitations as coverage for recipients who do not reside in institutions. A wheelchair

1.17 purchased outside of the facility's payment rate is the property of the recipient.

1.18 (b) Vendors of durable medical equipment, prosthetics, orthotics, or medical supplies

1.19 must enroll as a Medicare provider.

1.20 (c) When necessary to ensure access to durable medical equipment, prosthetics, orthotics,

1.21 or medical supplies, the commissioner may exempt a vendor from the Medicare enrollment

1.22 requirement if:

1.23 (1) the vendor supplies only one type of durable medical equipment, prosthetic, orthotic,

1.24 or medical supply;

2.1 (2) the vendor serves ten or fewer medical assistance recipients per year;

2.2 (3) the commissioner finds that other vendors are not available to provide same or similar
2.3 durable medical equipment, prosthetics, orthotics, or medical supplies; and

2.4 (4) the vendor complies with all screening requirements in this chapter and Code of
2.5 Federal Regulations, title 42, part 455. The commissioner may also exempt a vendor from
2.6 the Medicare enrollment requirement if the vendor is accredited by a Centers for Medicare
2.7 and Medicaid Services approved national accreditation organization as complying with the
2.8 Medicare program's supplier and quality standards and the vendor serves primarily pediatric
2.9 patients.

2.10 (d) Durable medical equipment means a device or equipment that:

2.11 (1) can withstand repeated use;

2.12 (2) is generally not useful in the absence of an illness, injury, or disability; and

2.13 (3) is provided to correct or accommodate a physiological disorder or physical condition
2.14 or is generally used primarily for a medical purpose.

2.15 (e) Electronic tablets may be considered durable medical equipment if the electronic
2.16 tablet will be used as an augmentative and alternative communication system as defined
2.17 under subdivision 31a, paragraph (a). To be covered by medical assistance, the device must
2.18 be locked in order to prevent use not related to communication.

2.19 (f) Notwithstanding the requirement in paragraph (e) that an electronic tablet must be
2.20 locked to prevent use not as an augmentative communication device, a recipient of waiver
2.21 services may use an electronic tablet for a use not related to communication when the
2.22 recipient has been authorized under the waiver to receive one or more additional applications
2.23 that can be loaded onto the electronic tablet, such that allowing the additional use prevents
2.24 the purchase of a separate electronic tablet with waiver funds.

2.25 (g) An order or prescription for medical supplies, equipment, or appliances must meet
2.26 the requirements in Code of Federal Regulations, title 42, part 440.70.

2.27 (h) Allergen-reducing products provided according to subdivision 67, paragraph (c) or
2.28 (d), shall be considered durable medical equipment.

2.29 (i) Enteral nutrition and supplies provided according to subdivision 31d must not be
2.30 considered medical supplies and equipment under this subdivision.

3.1 Sec. 2. Minnesota Statutes 2020, section 256B.0625, is amended by adding a subdivision
3.2 to read:

3.3 Subd. 31d. **Pediatric home-based enteral nutrition services.** Medical assistance covers
3.4 enteral nutrition, supplies, equipment, and services provided to patients 21 years of age or
3.5 younger receiving enteral nutrition in the patient's home residence and who are dependent
3.6 on a feeding tube for at least 75 percent of their nutritional needs. Pediatric home-based
3.7 enteral nutrition services must be provided according to the applicable requirements under
3.8 sections 256B.0651, 256B.0652, and 256B.066.

3.9 Sec. 3. Minnesota Statutes 2020, section 256B.0625, subdivision 32, is amended to read:

3.10 Subd. 32. **Nutritional products.** (a) Medical assistance covers nutritional products
3.11 needed for nutritional supplementation because solid food or nutrients thereof cannot be
3.12 properly absorbed by the body or needed for treatment of phenylketonuria, hyperlysinemia,
3.13 maple syrup urine disease, a combined allergy to human milk, cow's milk, and soy formula,
3.14 or any other childhood or adult diseases, conditions, or disorders identified by the
3.15 commissioner as requiring a similarly necessary nutritional product. Nutritional products
3.16 needed for the treatment of a combined allergy to human milk, cow's milk, and soy formula
3.17 require prior authorization.

3.18 (b) Separate payment ~~shall~~ must not be made for nutritional products for residents of
3.19 long-term care facilities. Payment for dietary requirements is a component of the per diem
3.20 rate paid to these facilities.

3.21 (c) Separate payment must not be made for nutritional products included in the payment
3.22 rate for pediatric home-based enteral nutrition services.

3.23 Sec. 4. Minnesota Statutes 2020, section 256B.0651, subdivision 1, is amended to read:

3.24 Subdivision 1. **Definitions.** (a) For the purposes of sections 256B.0651 to 256B.0654
3.25 and 256B.0659 to 256B.066, the terms in paragraphs (b) to (g) have the meanings given.

3.26 (b) "Activities of daily living" has the meaning given in section 256B.0659, subdivision
3.27 1, paragraph (b).

3.28 (c) "Assessment" means a review and evaluation of a recipient's need for home care
3.29 services conducted in person.

3.30 (d) "Home care services" means medical assistance covered services that are home health
3.31 agency services, including skilled nurse visits; home health aide visits; physical therapy,
3.32 occupational therapy, respiratory therapy, and language-speech pathology therapy; home

4.1 care nursing; ~~and~~ personal care assistance; and pediatric home-based enteral nutrition
 4.2 services.

4.3 (e) "Home residence," effective January 1, 2010, means a residence owned or rented by
 4.4 the recipient either alone, with roommates of the recipient's choosing, or with an unpaid
 4.5 responsible party or legal representative; or a family foster home where the license holder
 4.6 lives with the recipient and is not paid to provide home care services for the recipient except
 4.7 as allowed under sections 256B.0652, subdivision 10, and 256B.0654, subdivision 4.

4.8 (f) "Medically necessary" has the meaning given in Minnesota Rules, parts 9505.0170
 4.9 to 9505.0475.

4.10 (g) "Ventilator-dependent" means an individual who receives mechanical ventilation
 4.11 for life support at least six hours per day and is expected to be or has been dependent on a
 4.12 ventilator for at least 30 consecutive days.

4.13 Sec. 5. Minnesota Statutes 2020, section 256B.0651, subdivision 2, is amended to read:

4.14 Subd. 2. **Services covered.** Home care services covered under this section and sections
 4.15 256B.0652 to 256B.0654 and 256B.0659 to 256B.066 include:

4.16 (1) nursing services under sections 256B.0625, subdivision 6a, and 256B.0653;

4.17 (2) home care nursing services under sections 256B.0625, subdivision 7, and 256B.0654;

4.18 (3) home health services under sections 256B.0625, subdivision 6a, and 256B.0653;

4.19 (4) personal care assistance services under sections 256B.0625, subdivision 19a, and
 4.20 256B.0659;

4.21 (5) supervision of personal care assistance services provided by a qualified professional
 4.22 under sections 256B.0625, subdivision 19a, and 256B.0659;

4.23 (6) face-to-face assessments by county public health nurses for services under sections
 4.24 256B.0625, subdivision 19a, and 256B.0659; ~~and~~

4.25 (7) service updates and review of temporary increases for personal care assistance
 4.26 services by the county public health nurse for services under sections 256B.0625, subdivision
 4.27 19a, and 256B.0659; and

4.28 (8) pediatric home-based enteral nutrition services under sections 256B.0625, subdivision
 4.29 31d, and 256B.066.

5.1 Sec. 6. Minnesota Statutes 2020, section 256B.0652, subdivision 2, is amended to read:

5.2 Subd. 2. **Duties.** (a) The commissioner may contract with or employ necessary staff, or
5.3 contract with qualified agencies, to provide home care authorization and review services
5.4 for medical assistance recipients who are receiving home care services.

5.5 (b) Reimbursement for the authorization function shall be made through the medical
5.6 assistance administrative authority. The state shall pay the nonfederal share. The functions
5.7 will be to:

5.8 (1) assess the recipient's individual need for services required to be cared for safely in
5.9 the community;

5.10 (2) ensure that a care plan that meets the recipient's needs is developed by the appropriate
5.11 agency or individual;

5.12 (3) ensure cost-effectiveness and nonduplication of medical assistance home care services;

5.13 (4) recommend the approval or denial of the use of medical assistance funds to pay for
5.14 home care services;

5.15 (5) reassess the recipient's need for and level of home care services at a frequency
5.16 determined by the commissioner;

5.17 (6) conduct on-site assessments when determined necessary by the commissioner and
5.18 recommend changes to care plans that will provide more efficient and appropriate home
5.19 care; and

5.20 (7) on the department's website:

5.21 (i) provide a link to MinnesotaHelp.info for a list of enrolled home care agencies with
5.22 the following information: main office address, contact information for the agency, counties
5.23 in which services are provided, type of home care services provided, whether the personal
5.24 care assistance choice option is offered, types of qualified professionals employed, number
5.25 of personal care assistants employed, and data on staff turnover; and

5.26 (ii) post data on home care services including information from both fee-for-service and
5.27 managed care plans on recipients as available.

5.28 (c) In addition, the commissioner or the commissioner's designee may:

5.29 (1) review care plans, service plans, and reimbursement data for utilization of services
5.30 that exceed community-based standards for home care, inappropriate home care services,
5.31 medical necessity, home care services that do not meet quality of care standards, or

6.1 unauthorized services and make appropriate referrals within the department or to other
6.2 appropriate entities based on the findings;

6.3 (2) assist the recipient in obtaining services necessary to allow the recipient to remain
6.4 safely in or return to the community;

6.5 (3) coordinate home care services with other medical assistance services under section
6.6 256B.0625;

6.7 (4) assist the recipient with problems related to the provision of home care services;

6.8 (5) assure the quality of home care services; and

6.9 (6) assure that all liable third-party payers including, but not limited to, Medicare have
6.10 been used prior to medical assistance for home care services.

6.11 (d) For the purposes of this section, "home care services" means medical assistance
6.12 services defined under section 256B.0625, subdivisions 6a, 7, ~~and 19a~~, and 31d.

6.13 Sec. 7. Minnesota Statutes 2020, section 256B.0652, is amended by adding a subdivision
6.14 to read:

6.15 Subd. 6a. **Authorization; pediatric home-based enteral nutrition services.** All pediatric
6.16 home-based enteral nutrition services must be authorized by the commissioner or the
6.17 commissioner's designee. Authorization for pediatric home-based enteral nutrition services
6.18 must be based on medical necessity and cost-effectiveness when compared with alternative
6.19 care options. The commissioner must receive the request for authorization of pediatric
6.20 home-based enteral nutrition services within 20 working days of the start of service. The
6.21 commissioner may authorize medically necessary pediatric home-based enteral nutrition
6.22 services in monthly units. When authorizing pediatric home-based enteral nutrition services,
6.23 the commissioner or the commissioner's designee must determine to which tier the patient
6.24 should be assigned according to the definitions under section 256B.066. If the commissioner
6.25 or the commissioner's designee lacks sufficient information to determine to which tier a
6.26 patient should be assigned, the patient must be assigned to the lowest tier. Upon receipt of
6.27 information sufficient to reassign a patient to a higher tier, the commissioner or the
6.28 commissioner's designee must reassign the patient and within 30 days the commissioner
6.29 must modify the payment rates accordingly.

6.30 Sec. 8. Minnesota Statutes 2020, section 256B.0652, subdivision 11, is amended to read:

6.31 Subd. 11. **Limits on services without authorization.** A recipient may receive the
6.32 following home care services during a calendar year:

7.1 (1) up to two face-to-face assessments to determine a recipient's need for personal care
7.2 assistance services;

7.3 (2) one service update done to determine a recipient's need for personal care assistance
7.4 services; ~~and~~

7.5 (3) up to nine face-to-face skilled nurse visits; and

7.6 (4) up to two months of pediatric home-based enteral nutrition services.

7.7 **Sec. 9. [256B.066] PEDIATRIC HOME-BASED ENTERAL NUTRITION SERVICES.**

7.8 **Subdivision 1. Definitions.** (a) For the purposes of this section, the following terms have
7.9 the meanings given.

7.10 (b) "Base care rate" means the case rate for a patient ten years of age or younger.

7.11 (c) "Case rate" means the monthly bundled payment rate paid to a pediatric home-based
7.12 enteral nutrition services provider as reimbursement for all nutritional products, medical
7.13 supplies and equipment, and covered services provided to a patient receiving pediatric
7.14 home-based enteral nutrition services.

7.15 (d) "Pediatric patient" means a patient 21 years of age or younger.

7.16 (e) "Rate year" means January 1 to December 31.

7.17 (f) "Tier one patient" means a pediatric patient who is dependent on a feeding tube for
7.18 at least 75 percent of the patient's nutritional needs.

7.19 (g) "Tier two patient" means a pediatric patient who is dependent on a feeding tube for
7.20 at least 75 percent of the patient's nutritional needs and who has multiple diagnoses or
7.21 significantly higher needs than a tier one patient or is at risk of infections or complications.

7.22 **Subd. 2. Pediatric home-based enteral nutrition services.** (a) Pediatric home-based
7.23 enteral nutrition services include the provision of the following nutritional products and
7.24 medical supplies and equipment for tier one and tier two patients: formula, feeding tubes,
7.25 extension sets, dressings, tape, syringes, feeding sets, gravity bags, venting systems,
7.26 declogging agents, securement devices, food pumps, IV poles, and backpacks.

7.27 (b) Pediatric home-based enteral nutrition services include the provision of the following
7.28 services for tier one patients: patient intake, ordering, clinical set-up, clinical troubleshooting,
7.29 ongoing shipment or delivery of nutritional products and medical supplies and equipment,
7.30 equipment maintenance and management, and interpreter use.

8.1 (c) Pediatric home-based enteral nutrition services include the provision of the following
8.2 services for tier two patients: the services described in paragraph (b), clinical dietitian
8.3 assessments, clinical dietitian reassessments, clinical dietitian follow-up, and skilled nursing
8.4 for the purposes of supporting achievement of quality metrics under subdivision 4.

8.5 Subd. 3. **Noncovered services.** The following enteral nutrition, supplies, equipment,
8.6 and services are not eligible for payment under medical assistance as pediatric home-based
8.7 enteral nutrition services:

8.8 (1) those provided to patients 22 years of age or older; and

8.9 (2) those provided to a pediatric patient who does not meet the definition of a tier one
8.10 or tier two patient.

8.11 Subd. 4. **Quality metrics.** For the purposes of developing incentive programs under
8.12 subdivisions 7 and 8, in consultation with stakeholders, the commissioner must develop
8.13 methods to measure and report the following:

8.14 (1) care plan completion;

8.15 (2) clinical follow-up and assessments;

8.16 (3) tier two patients meeting their weight goals;

8.17 (4) triage prior to avoidable complications;

8.18 (5) avoidable emergency room visits;

8.19 (6) feeding tube site management and skin integrity;

8.20 (7) care coordination; and

8.21 (8) patient and caregiver satisfaction.

8.22 Subd. 5. **Base case rates for pediatric home-based enteral nutrition services.** (a) The
8.23 base case rate for tier one patients is \$862 per patient per month.

8.24 (b) The base case rate for tier two patients is \$1,083 per patient per month.

8.25 Subd. 6. **Age-based case rate modifiers.** (a) The age-based case rate modifier for patients
8.26 who are 11 or 12 years of age is \$233 per patient per month.

8.27 (b) The age-based case rate modifier for patients who are 13 years of age or older is
8.28 \$429 per patient per month.

8.29 Subd. 7. **Quality metric reporting incentives.** The commissioner must develop a quality
8.30 metric reporting incentive program in consultation with stakeholders. The annual funding

9.1 pool available for quality metric reporting incentive payments must be equal to three percent
9.2 of the estimated state expenditures during rate year 2023 for pediatric home-based enteral
9.3 nutrition services exclusive of any incentive payments. For services provided between
9.4 January 1, 2023, and December 31, 2025, providers of pediatric home-based enteral nutrition
9.5 services are eligible for quality metric reporting payments for meeting quality metric reporting
9.6 standards established by the commissioner.

9.7 Subd. 8. **Quality improvement incentives.** The commissioner must develop a quality
9.8 improvement incentive program in consultation with stakeholders. The annual funding pool
9.9 available for quality improvement incentive payments must be equal to three percent of the
9.10 estimated state expenditures during rate year 2026 for pediatric home-based enteral nutrition
9.11 services exclusive of any incentive payments. For services provided after January 1, 2026,
9.12 providers of pediatric home-based enteral nutrition services are eligible for quality
9.13 improvement payments for meeting quality improvement goals established by the
9.14 commissioner.

9.15 Subd. 9. **Total payment rate.** The total per-patient, per-month payment for pediatric
9.16 home-based enteral nutrition services is the sum of the base care rate, the age-based case
9.17 rate modifier, and any applicable incentive payment under subdivision 7 or 8.

9.18 Sec. 10. Minnesota Statutes 2020, section 256B.766, is amended to read:

9.19 **256B.766 REIMBURSEMENT FOR BASIC CARE SERVICES.**

9.20 (a) Effective for services provided on or after July 1, 2009, total payments for basic care
9.21 services, shall be reduced by three percent, except that for the period July 1, 2009, through
9.22 June 30, 2011, total payments shall be reduced by 4.5 percent for the medical assistance
9.23 and general assistance medical care programs, prior to third-party liability and spenddown
9.24 calculation. Effective July 1, 2010, the commissioner shall classify physical therapy services,
9.25 occupational therapy services, and speech-language pathology and related services as basic
9.26 care services. The reduction in this paragraph shall apply to physical therapy services,
9.27 occupational therapy services, and speech-language pathology and related services provided
9.28 on or after July 1, 2010.

9.29 (b) Payments made to managed care plans and county-based purchasing plans shall be
9.30 reduced for services provided on or after October 1, 2009, to reflect the reduction effective
9.31 July 1, 2009, and payments made to the plans shall be reduced effective October 1, 2010,
9.32 to reflect the reduction effective July 1, 2010.

10.1 (c) Effective for services provided on or after September 1, 2011, through June 30, 2013,
10.2 total payments for outpatient hospital facility fees shall be reduced by five percent from the
10.3 rates in effect on August 31, 2011.

10.4 (d) Effective for services provided on or after September 1, 2011, through June 30, 2013,
10.5 total payments for ambulatory surgery centers facility fees, medical supplies and durable
10.6 medical equipment not subject to a volume purchase contract, prosthetics and orthotics,
10.7 renal dialysis services, laboratory services, public health nursing services, physical therapy
10.8 services, occupational therapy services, speech therapy services, eyeglasses not subject to
10.9 a volume purchase contract, hearing aids not subject to a volume purchase contract, and
10.10 anesthesia services shall be reduced by three percent from the rates in effect on August 31,
10.11 2011.

10.12 (e) Effective for services provided on or after September 1, 2014, payments for
10.13 ambulatory surgery centers facility fees, hospice services, renal dialysis services, laboratory
10.14 services, public health nursing services, eyeglasses not subject to a volume purchase contract,
10.15 and hearing aids not subject to a volume purchase contract shall be increased by three percent
10.16 and payments for outpatient hospital facility fees shall be increased by three percent.
10.17 Payments made to managed care plans and county-based purchasing plans shall not be
10.18 adjusted to reflect payments under this paragraph.

10.19 (f) Payments for medical supplies and durable medical equipment not subject to a volume
10.20 purchase contract, and prosthetics and orthotics, provided on or after July 1, 2014, through
10.21 June 30, 2015, shall be decreased by .33 percent. Payments for medical supplies and durable
10.22 medical equipment not subject to a volume purchase contract, and prosthetics and orthotics,
10.23 provided on or after July 1, 2015, shall be increased by three percent from the rates as
10.24 determined under paragraphs (i) and (j).

10.25 (g) Effective for services provided on or after July 1, 2015, payments for outpatient
10.26 hospital facility fees, medical supplies and durable medical equipment not subject to a
10.27 volume purchase contract, prosthetics, and orthotics to a hospital meeting the criteria specified
10.28 in section 62Q.19, subdivision 1, paragraph (a), clause (4), shall be increased by 90 percent
10.29 from the rates in effect on June 30, 2015. Payments made to managed care plans and
10.30 county-based purchasing plans shall not be adjusted to reflect payments under this paragraph.

10.31 (h) This section does not apply to physician and professional services, inpatient hospital
10.32 services, family planning services, mental health services, dental services, prescription
10.33 drugs, medical transportation, federally qualified health centers, rural health centers, Indian
10.34 health services, and Medicare cost-sharing.

11.1 (i) Effective for services provided on or after July 1, 2015, the following categories of
11.2 medical supplies and durable medical equipment shall be individually priced items: enteral
11.3 nutrition and supplies not included in the payment rate for pediatric home-based enteral
11.4 nutrition services under section 256B.0625, subdivision 31d, customized and other specialized
11.5 tracheostomy tubes and supplies, electric patient lifts, and durable medical equipment repair
11.6 and service. This paragraph does not apply to medical supplies and durable medical
11.7 equipment subject to a volume purchase contract, products subject to the preferred diabetic
11.8 testing supply program, and items provided to dually eligible recipients when Medicare is
11.9 the primary payer for the item. The commissioner shall not apply any medical assistance
11.10 rate reductions to durable medical equipment as a result of Medicare competitive bidding.

11.11 (j) Effective for services provided on or after July 1, 2015, medical assistance payment
11.12 rates for durable medical equipment, prosthetics, orthotics, or supplies shall be increased
11.13 as follows:

11.14 (1) payment rates for durable medical equipment, prosthetics, orthotics, or supplies that
11.15 were subject to the Medicare competitive bid that took effect in January of 2009 shall be
11.16 increased by 9.5 percent; and

11.17 (2) payment rates for durable medical equipment, prosthetics, orthotics, or supplies on
11.18 the medical assistance fee schedule, whether or not subject to the Medicare competitive bid
11.19 that took effect in January of 2009, shall be increased by 2.94 percent, with this increase
11.20 being applied after calculation of any increased payment rate under clause (1).

11.21 This paragraph does not apply to medical supplies and durable medical equipment subject
11.22 to a volume purchase contract, products subject to the preferred diabetic testing supply
11.23 program, items provided to dually eligible recipients when Medicare is the primary payer
11.24 for the item, and individually priced items identified in paragraph (i). Payments made to
11.25 managed care plans and county-based purchasing plans shall not be adjusted to reflect the
11.26 rate increases in this paragraph.

11.27 (k) Effective for nonpressure support ventilators provided on or after January 1, 2016,
11.28 the rate shall be the lower of the submitted charge or the Medicare fee schedule rate. Effective
11.29 for pressure support ventilators provided on or after January 1, 2016, the rate shall be the
11.30 lower of the submitted charge or 47 percent above the Medicare fee schedule rate. For
11.31 payments made in accordance with this paragraph, if, and to the extent that, the commissioner
11.32 identifies that the state has received federal financial participation for ventilators in excess
11.33 of the amount allowed effective January 1, 2018, under United States Code, title 42, section

- 12.1 1396b(i)(27), the state shall repay the excess amount to the Centers for Medicare and
12.2 Medicaid Services with state funds and maintain the full payment rate under this paragraph.
- 12.3 (l) Payment rates for durable medical equipment, prosthetics, orthotics or supplies, that
12.4 are subject to the upper payment limit in accordance with section 1903(i)(27) of the Social
12.5 Security Act, shall be paid the Medicare rate. Rate increases provided in this chapter shall
12.6 not be applied to the items listed in this paragraph.