

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-06-16

**DATE:** May 11, 2006  
**TO:** State Survey Agency Directors  
**FROM:** Director  
Survey and Certification Group  
**SUBJECT:** Nursing Homes and Medicare Part D

**Letter Summary**

This memorandum clarifies residents' rights regarding choice of a prescription drug plan and pharmacy provider, the nursing homes' responsibility to provide drugs to residents, and State Survey Agencies' responsibilities with respect to the new Medicare prescription drug benefit and nursing homes:

- Residents have the right to make informed decision/choices about their care as described in sections §1802, §1851 and §1860 of the Social Security Act and 42 C.F.R. Part 483;
- Residents are guaranteed the right to choose a Part D **plan**, but do not have unbridled freedom to choose a **pharmacy**; and
- We expect nursing homes to work with their current pharmacies to assure that they recognize the Part D plans chosen by that facility's Medicare beneficiaries, or, in the alternative, to add additional pharmacies to achieve that objective. Or, at its option, the facility could contract exclusively with another pharmacy that contracts more broadly with Part D plans.

The purpose of this memorandum is to:

1. Answer questions surrounding nursing home pharmacy services following the January 01, 2006, implementation of the new Medicare prescription drug benefit relative to the:
  - Residents' right to choose their drug plan and pharmacy,
  - Nursing homes' regulatory compliance responsibilities, and
  - Surveyors' responsibilities.
2. Provide surveyors with a list of nursing home regulations that appear pertinent to the implementation of the Medicare Drug Benefit (Part D). The list is not exhaustive (Attachment A).

3. Provide surveyors with reference resources relative to Medicare Part D and nursing homes regulatory requirements (Attachments B&C).
4. Reinforce our commitment to provide high quality care and services to all beneficiaries.

### **Resident Rights**

The freedom of choice provisions at sections §1802 and §1902(a)(23) of the Social Security Act provide that any individual entitled to insurance benefits under Medicare or Medicaid may obtain health services from any institution, agency, or person qualified to participate under this title. In addition, residents are guaranteed the right to choose their Medicare Prescription Drug Benefit Plan at section §1860D of the Social Security Act.

These provisions do not, however, give unbridled freedom of choice for nursing home residents to choose a pharmacy, with the exception of those states with a “right-to-choose” state law. Sections 1819(b)(4)(A)(iii) and 1919(b)(4)(A)(iii) of the Social Security Act require a skilled nursing facility and a nursing facility, respectively, to provide “pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals to meet the needs of each resident).” We believe these statutory provisions place the responsibility for accurately administering drugs on the nursing home and with that responsibility the right to define certain standards for labeling, packaging, storage, processing, and administration of drugs. These standards are essential in assuring that the resident is protected from medication errors.

Nursing home residents, like all other Medicare beneficiaries, have a right to choose their Part D plans. The statute, at section 1860D-1, and implementing regulations at 42 C.F.R. 423.32, ensure that right and do not lessen that right simply by virtue of the beneficiary's admission to a nursing facility. There may be cases where a nursing home acts in a way that frustrates a beneficiary's ability to receive cost effective coverage under Part D for needed prescription drugs under his or her preferred plan. For example, where the facility exclusively engages a pharmacy that does not have an arrangement with the Part D plan selected by the beneficiary, the beneficiary may be unable to obtain coverage of needed drugs through his or her Part D plan, and may incur higher Part D premiums and/or cost sharing if he or she must switch to an alternative plan in order to receive Part D coverage of his or her drugs. Or, a facility may overreach its authority and try to steer a resident to one or more Part D plans preferred by the facility or its pharmacy. Residents in such cases might feel compelled to choose another Part D plan that may not best satisfy their needs in order to conform to the wishes of the facility and its pharmacy. Such facility behavior would violate its obligations under the facility requirements of participation at 42 C.F.R. 483.12(d) which prohibit a facility from requiring residents to waive their Medicare rights. Additionally, failure by a facility to permit residents to receive coverage of needed drugs that would be available from the Part D plan of their choosing could constitute a violation of the facility's pharmacy obligations under 42 C.F.R. 483.60 which obligates facilities to acquire all drugs that meet the needs of each resident. Accordingly, we expect nursing homes to not frustrate a beneficiary's choice in Part D plans, and to work with pharmacies to make sure that a resident's choices are honored so that there is no disruption in the provision of necessary drugs. Specifically, we expect nursing homes to work with their current pharmacies to assure that they recognize the Part D plans chosen by that facility's Medicare beneficiaries, or, in the alternative, to add additional pharmacies to achieve that objective. Or, at its option, the facility could contract exclusively with another pharmacy that contracts more broadly with Part D plans.

## **Facility Regulatory Compliance Responsibility**

Nursing homes must have a safe and accurate system for the delivery of medications to their residents. While nursing homes are free to use multiple pharmacies, the first priority of 42 C.F.R. 483.60 is to assure that nursing homes provide needed medications for each resident, without errors.” Therefore, safety should be considered when making determinations relative to the residents’ medications.

Since nursing homes are responsible for the safety and efficacy of the medication delivery system to their residents, they hold the responsibility for selecting a pharmacy or pharmacies that are willing and able to accommodate the Medicare Prescription Drug Benefit Plans chosen by all residents of their nursing home.

Under no circumstances should a nursing home require, request, coach, or steer any resident to select or change a plan for any reason. Furthermore, a nursing home should not knowingly and/or willingly allow the pharmacy servicing the nursing home to require, request, coach, or steer any resident to select or change a plan [42 C.F.R. §483.12(d)]. Nursing homes may, and are encouraged to, provide information and education to residents on all available Part D plans.

Nursing homes should provide residents with an explanation, on admission or immediately if the resident is already in the nursing home at the time of the plan implementation, of their right to choose their prescription drug benefit plan [42 C.F.R. §483.12(d)].

## **Surveyor Responsibility**

State Survey Agencies will continue to monitor nursing homes for compliance with regulations as outlined in the regulations at 42 C.F.R. Part 483 and accompanying surveyor guidance. For example, surveyors should cite §483.60 (F426) if nursing homes are not providing pharmaceutical services to meet the need of each resident.

To the extent a survey or complaint investigation finds the resident’s right to choose a Part D plan is denied as a result of pharmacy limitations, or for any other reason, surveyors should:

- Educate nursing home administrators as to the distinction between a resident’s choices of plans, the nursing home’s choice of pharmacies, and the nursing home’s responsibility to protect the resident’s right to Part D plan choices.
- Cite §483.12(d) (F208) if residents are denied the right to select their prescription drug plan, and encourage the nursing home to develop and implement an effective and timely plan of correction.

## **CMS’ Survey and Certification Program**

If a complaint involves both a CMS regulatory requirement for nursing homes (such as the residents’ rights issue discussed above) and a Part D requirement, the surveyor should act on the survey issue and also notify the appropriate Part D authority.

The appropriate Part D authority is the Part D case manager working in your region.

For further information please contact Debra Swinton-Spears at (410) 786 -7506 or e-mail at [debra.swinton-spears@cms.hhs.gov](mailto:debra.swinton-spears@cms.hhs.gov).

**Effective Date:** Immediately. Please ensure that all appropriate staff are informed within 30 days of the date of this memorandum, and disseminate the information to affected providers.

**Training:** The information contained in this announcement should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachments

**SNF Requirements (42 CFR Part 483) for Certification  
And The Medicare Drug Benefit (Part D)  
Updated January 6, 2006**

The following skilled nursing facility regulations appear to be pertinent to the implementation of the Medicare Drug Benefit (Part D). This list is not all inclusive.

**483.60 Pharmacy Services. (F425)** “The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.75(h) of this part.”

The Interpretive Guideline states: “A drug...must be provided in a timely manner. If failure to provide a prescribed drug in a timely manner causes the resident discomfort or endangers his or her health and safety, then this requirement is not met.”

**483.60(a) Procedures. (F426)** “A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.”

**483.60(b) Service Consultation. (F427)** “The facility must employ or obtain the services of a licensed pharmacist who - Provides consultation on all aspects of the provision of pharmacy services in the facility;”

**483.75 Administration. (F490)** “A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.”

**483.75(b) Administration. (F492)** “Compliance with Federal, State, and local laws and professional standards. The facility must operate and provide services in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility.”

**483.75(i) Medical Director. (F501)** “(1) The facility must designate a physician to serve as medical director. (2) The medical director is responsible for – (i) Implementation of resident care policies; and (ii) The coordination of medical care in the facility.”

The Interpretive Guideline states: “The medical director has a key role in helping the facility to incorporate current standards of practice into resident care policies and procedures/guidelines to help assure that they address the needs of the residents. Although regulations do not require the medical director to sign the policies or procedures, the facility should be able to show that its development, review, and approval of resident care policies included the medical director’s input.

This requirement does not imply that the medical director must carry out the policies and procedures or supervise staff performance directly, but rather must guide, approve, and help oversee the implementation of the policies and procedures. Examples of resident care policies include, but are not limited to:

- The integrated delivery of care and services, such as medical, nursing, pharmacy, social, rehabilitative and dietary services, which includes clinical assessments, analysis of assessment findings, care planning including preventive care, care plan monitoring and modification, infection control (including isolation or special care), transfers to other settings, and discharge planning;”

**483.15(g) Social Services. (F250)** “The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.”

The Interpretive Guideline states: “ ‘Medically-related social services’ means services provided by the facility’s staff to assist residents in maintaining or improving their ability to manage their everyday physical, mental, and psychosocial needs. These services might include, for example:

- Assisting staff to inform residents and those they designate about the residents health status and health care choices and their ramifications;
- Making referrals and obtaining services from outside entities;
- Assisting residents with financial and legal matters;
- Through assessment and care planning process, identifying and seeking ways to support residents’ individual needs;
- Assisting residents to determine how they would like to make decisions about their health care; and
- Finding options that most meet the physical and emotional needs of each resident.”

“When needed services are not covered by the Medicaid State plan, nursing facilities are still required to attempt to obtain these services.”

**483.10(a)(1) Exercise of Rights. (F151)** “The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.”

**483.10(b)(6) Right to be Informed. (F156)** “The facility must inform each resident before, or at the time of admission and periodically during the resident’s stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility’s per diem rate.”

**483.10(b)(10) Right to be Informed. (F156)** “The facility must prominently display in the facility written information, and provide to residents and applicants for admission oral and written information about how to apply for and use Medicare and Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.”

**483.10(c)(8) Limitation on Charges to Resident Funds. (F162)** “The facility may not impose a charge against the personal funds of a resident for any item or services for which payment is made under Medicaid or Medicare (except for applicable deductible and coinsurance amounts).”

(Drugs and pharmaceuticals are not listed.)

**483.10(j)(2) Access and Visitation Rights. (F172)** “The facility must provide reasonable access to any resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident’s right to deny or withdraw consent at any time.”

**483.12(d) (1) Admissions Policy (F208)** “The facility must--(i) Not require residents or potential residents to waive their rights to Medicare or Medicaid.”

**List of Internet Websites/References  
Support Tool for Long Term Care Surveyors**

**Medicare Part D: Impact on Nursing Home Surveys – send satellite broadcast questions and/or comments to**

[SCG\\_DNH\\_MedicarePartD@cms.hhs.gov](mailto:SCG_DNH_MedicarePartD@cms.hhs.gov)

**Medicare Part D Webcast: Available through May 2006**

<http://www.cms.hhs.gov/partnerships/news/mma/webcasts.asp>

**The Centers for Medicare & Medicaid Services (CMS) – State Operations Manual (SOM) Chapters and Appendices**

<http://www.cms.hhs.gov/manuals/>

- Click internet only manuals (IOMs) to the left of your screen
- Scroll down the page and click 100.07 publication
- Scroll down to the bottom of the site page and click on the Appendices Table of Contents

**Long Term Care Guidance**

[http://www.cms.hhs.gov/pdps/LTC\\_guidance.pdf](http://www.cms.hhs.gov/pdps/LTC_guidance.pdf)

**Locating Prescription Drug Plans and Medicare Advantage Plans in Your Area**

[www.cms.hhs.gov/map/map.asp](http://www.cms.hhs.gov/map/map.asp)

**Medicare prescription Drug Plan Cost Estimator Tool**

[www.medicare.gov/medicarereform/MPDP\\_Cost\\_Estimator.asp](http://www.medicare.gov/medicarereform/MPDP_Cost_Estimator.asp)

**Comprehensive Resource Kit**

<http://www.cms.hhs.gov/partnerships/tools/materials/medicaretraining/hihresourcekit/default.asp>

**Medicare Prescription Drug Coverage Toolkit**

<http://www.cms.hhs.gov/partnerships/tools/materials/medicaretraining/MPDCoutreachkit.asp>

**Medicare Prescription Drug Plan Finder Training Demonstration**

<http://media.cms.hhs.gov/>

**Online Training Modules**

<http://www.cms.hhs.gov/partnerships/tools/materials/medicaretraining/default.htm>

**Medlearn Matters**

<http://www.cms.hhs.gov/medlearn/matters/>

**Medicare Spotlights 1-800-MEDICARE**

<http://www.medicare.gov/>

**CMS – Guidance to State Survey Agency Directors and Regional Offices (Survey & Certification Letters)**

<http://www.cms.hhs.gov/SurveyCertificationGenInfo/>

- Generally, survey and certification letters are issued on the second Thursday of every month; however, they may be issued “off cycle.” These letters contain policy instructions and updates. Letters are available on the internet within a week after issuance.

**CMS – Sharing Innovations in Quality (Repository of Clinical Standards and Guidelines)**

<http://siq.air.org>

- “Sharing Innovations in Quality” (SIQ) is a repository of information on clinical standards and guidelines useful to surveyors and to professionals in the nursing home setting. SIQ is sponsored by CMS and hosted by the American Institutes for Research (AIR). The guidelines are examined annually to assure that they are up-to-date, and new ones are added on a continuous basis.

**CMS – Medicare Quality Improvement**

<http://www.medqic.org>

- CMS developed this online resource of quality improvement information for Medicare's National Quality Improvement Priorities.

**CMS – Survey and Certification Training**

<http://www.cms.hhs.gov/SurveyorTraining/>

**CMS – Satellite Training at internet streamline**

<http://cms.internetstreaming.com/>

- We recommend that you bookmark this site, as your "home" for CMS Surveyor Courses.

**CMS – Minimum Data Set training**

<http://www.mdstraining.org/upfront/u1.asp>

- Web-Based Lessons course for Resident Assessment Instrument/Minimum Data Set (RAI/MDS) are posted here in the form of modules.

**CMS – RAI/MDS manual**

<http://www.cms.hhs.gov/quality/mds20/>

**Environmental Protection Agency**

<http://www.epa.gov>

**Prescription Drugs Guide**

[www.Epocrates.com](http://www.Epocrates.com)

**The Association for Professionals in Infection Control and Epidemiology, Inc. (APIC)**

<http://www.apic.org>

**The American Association of Nurse Assessment Coordinators (AANAC)**

<http://www.aanac.org>

**The Alzheimer's Association**

<http://www.alz.org>

**The Centers for Disease Control and Prevention (CDC)**

<http://www.cdc.gov>

**U.S. Food and Drug Association (FDA)**

<http://www.fda.gov>

**FDA- Food Safety Information**

<http://www.foodsafety.gov>

**The American Diabetes Association**

<http://www.diabetes.org>

**The American Dietetic Association**

<http://www.eatright.org>

**The U.S. Department of Agriculture Food Safety and Inspection Service (FSIS)**

<http://www.fsis.usda.gov>

**Disability Resources**

<http://www.disability.gov>

**The Administration on Aging**

<http://www.aoa.gov>

**Social Security Act §1860D Part D – Voluntary Prescription Drug Benefit Program**

Subpart 1 – Part D Eligible Individuals and Prescription Drug Benefits

- SEC. 1860D-1. [42 U.S.C. 1395w-101]

*(a) PROVISION OF QUALIFIED PRESCRIPTION DRUG COVERAGE THROUGH ENROLLMENT IN PLANS.—*

(1) IN GENERAL.—Subject to the succeeding provisions of this part, each part D eligible individual (as defined in paragraph (3)(A)) is entitled to obtain qualified prescription drug coverage (described in section 1860D-2(a)) as follows:

(A) FEE-FOR-SERVICE ENROLLEES MAY RECEIVE COVERAGE THROUGH A PRESCRIPTION DRUG PLAN.—A part D eligible individual who is not enrolled in an MA plan may obtain qualified prescription drug coverage through enrollment in a prescription drug plan (as defined in section 1860D-41(a)(14)).

(B) MEDICARE ADVANTAGE ENROLLEES.—

(i) ENROLLEES IN A PLAN PROVIDING QUALIFIED PRESCRIPTION DRUG COVERAGE RECEIVE COVERAGE THROUGH THE PLAN.—A part D eligible individual who is enrolled in an MA-PD plan obtains such coverage through such plan.

(ii) LIMITATION ON ENROLLMENT OF MA PLAN ENROLLEES IN PRESCRIPTION DRUG PLANS.—Except as provided in clauses (iii) and (iv), a part D eligible individual who is enrolled in an MA plan may not enroll in a prescription drug plan under this part.

(iii) PRIVATE FEE-FOR-SERVICE ENROLLEES IN MA PLANS NOT PROVIDING QUALIFIED PRESCRIPTION DRUG COVERAGE PERMITTED TO ENROLL IN A PRESCRIPTION DRUG PLAN.—A part D eligible individual who is enrolled in an MA private fee-for-service plan (as defined in section [1859\(b\)\(2\)](#)) that does not provide qualified prescription drug coverage may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

(iv) ENROLLEES IN MSA A PLANS PERMITTED TO ENROLL IN A PRESCRIPTION DRUG PLAN.—A part D eligible individual who is enrolled in an MSA plan (as defined in section [1859\(b\)\(3\)](#)) may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

(2) COVERAGE FIRST EFFECTIVE JANUARY 1, 2006.—Coverage under prescription drug plans and MA-PD plans shall first be effective on January 1, 2006.

(3) DEFINITIONS.—For purposes of this part:

(A) PART D ELIGIBLE INDIVIDUAL.—The term “part D eligible individual” means an individual who is entitled to benefits under part A or enrolled under part B.

(B) MA PLAN.—The term “MA plan” has the meaning given such term in section [1859\(b\)\(1\)](#).

(C) MA-PD PLAN.—The term “MA-PD plan” means an MA plan that provides qualified prescription drug coverage.

*(b) ENROLLMENT PROCESS FOR PRESCRIPTION DRUG PLANS.—*

(1) ESTABLISHMENT OF PROCESS.—

(A) IN GENERAL.—The Secretary shall establish a process for the enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in prescription drug plans consistent with this subsection.

(B) APPLICATION OF MA RULES.—In establishing such process, the Secretary shall use rules similar to (and coordinated with) the rules for enrollment, disenrollment, termination, and change of enrollment with an MA-PD plan under the following provisions of section [1851](#):

- (i) RESIDENCE REQUIREMENTS.—Section [1851\(b\)\(1\)\(A\)](#), relating to residence requirements.

[ *SEC. 1851(b)(1)(A). RESIDENT REQUIREMENTS –SPECIAL RULES.*

(1) RESIDENCE REQUIREMENT.— (A) IN GENERAL.—Except as the Secretary may otherwise provide and except as provided in subparagraph (C), an individual is eligible to elect a Medicare+Choice plan offered by a Medicare+Choice organization only if the plan serves the geographic area in which the individual resides.]

- (ii) EXERCISE OF CHOICE.—Section [1851\(c\)](#) (other than paragraph (3)(A) of such section), relating to exercise of choice.

[*SEC. 1851(c) PROCESS FOR EXERCISING CHOICE.— (1) IN GENERAL.—*

The Secretary shall establish a process through which elections described in subsection (a) are made and changed, including the form and manner in which such elections are made and changed. Such elections shall be made or changed only during coverage election periods specified under subsection (e) and shall become effective as provided in subsection (f). (2) COORDINATION

THROUGH MEDICARE+CHOICE ORGANIZATIONS.— (A)

ENROLLMENT.—Such process shall permit an individual who wishes to elect a Medicare+Choice plan offered by a Medicare+Choice organization to make such election through the filing of an appropriate election form with the organization.

(B) DISENROLLMENT.—Such process shall permit an individual, who has elected a Medicare+Choice plan offered by a Medicare+Choice organization and who wishes to terminate such election, to terminate such election through the filing of an appropriate election form with the organization. (3) DEFAULT.— (A)

INITIAL ELECTION.— (i) IN GENERAL.—Subject to clause (ii), an individual who fails to make an election during an initial election period under subsection (e)(1) is deemed to have chosen the original Medicare fee-for-service program option. (ii) SEAMLESS CONTINUATION OF COVERAGE.—The Secretary

may establish procedures under which an individual who is enrolled in a health plan (other than Medicare+Choice plan) offered by a Medicare+Choice organization at the time of the initial election period and who fails to elect to receive coverage other than through the organization is deemed to have elected

the Medicare+Choice plan offered by the organization (or, if the organization offers more than one such plan, such plan or plans as the Secretary identifies under such procedures). (B) CONTINUING PERIODS.—An individual who has made (or is deemed to have made) an election under this section is considered to have continued to make such election until such time as— (i) the individual

changes the election under this section, or (ii) the Medicare+Choice plan with

respect to which such election is in effect is discontinued or, subject to subsection (b)(1)(B), no longer serves the area in which the individual resides.]

- (iii) **COVERAGE ELECTION PERIODS.**—Subject to paragraphs (2) and (3) of this subsection, section [1851\(e\)](#) (other than subparagraphs (B) and (C) of paragraph (2) and the second sentence of paragraph (4) of such section), relating to coverage election periods, including initial periods, annual coordinated election periods, special election periods, and election periods for exceptional circumstances.
- (iv) **COVERAGE PERIODS.**—Section [1851\(f\)](#), relating to effectiveness of elections and changes of elections.
- (v) **GUARANTEED ISSUE AND RENEWAL.**—Section [1851\(g\)](#) (other than paragraph (2) of such section and clause (i) and the second sentence of clause (ii) of paragraph (3)(C) of such section), relating to guaranteed issue and renewal.
- (vi) **MARKETING MATERIAL AND APPLICATION FORMS.**—Section [1851\(h\)](#), relating to approval of marketing material and application forms. In applying clauses (ii), (iv), and (v) of this subparagraph, any reference to section [1851\(e\)](#) shall be treated as a reference to such section as applied pursuant to clause (iii) of this subparagraph.

(C) **SPECIAL RULE.**—The process established under subparagraph (A) shall include, in the case of a part D eligible individual who is a full-benefit dual eligible individual (as defined in section [1935\(c\)\(6\)](#)) who has failed to enroll in a prescription drug plan or an MA-PD plan, for the enrollment in a prescription drug plan that has a monthly beneficiary premium that does not exceed the premium assistance available under section 1860D-14(a)(1)(A)). If there is more than one such plan available, the Secretary shall enroll such an individual on a random basis among all such plans in the PDP region. Nothing in the previous sentence shall prevent such an individual from declining or changing such enrollment.

(2) **INITIAL ENROLLMENT PERIOD.**—

(A) **PROGRAM INITIATION.**—In the case of an individual who is a part D eligible individual as of November 15, 2005, there shall be an initial enrollment period that shall be the same as the annual, coordinated open election period described in section [1851\(e\)\(3\)\(B\)\(iii\)](#), as applied under paragraph (1)(B)(iii).

(B) **CONTINUING PERIODS.**—In the case of an individual who becomes a part D eligible individual after November 15, 2005, there shall be an initial enrollment period which is the period under section [1851\(e\)\(1\)](#), as applied under paragraph (1)(B)(iii) of this section, as if “entitled to benefits under part A or enrolled under part B” were substituted for “entitled to benefits under part A and enrolled under part B”, but in no case shall such period end before the period described in subparagraph (A).

(3) **ADDITIONAL SPECIAL ENROLLMENT PERIODS.**—The Secretary shall establish special enrollment periods, including the following:

(A) **INVOLUNTARY LOSS OF CREDITABLE PRESCRIPTION DRUG COVERAGE.**—

(i) **IN GENERAL.**—In the case of a part D eligible individual who involuntarily loses creditable prescription drug coverage (as defined in section 1860D-13(b)(4)).

(ii) **NOTICE.**—In establishing special enrollment periods under clause (i), the Secretary shall take into account when the part D eligible individuals are provided notice of the loss of creditable prescription drug coverage.

(iii) FAILURE TO PAY PREMIUM.—For purposes of clause (i), a loss of coverage shall be treated as voluntary if the coverage is terminated because of failure to pay a required beneficiary premium.

(iv) REDUCTION IN COVERAGE.—For purposes of clause (i), a reduction in coverage so that the coverage no longer meets the requirements under section 1860D-13(b)(5) (relating to actuarial equivalence) shall be treated as an involuntary loss of coverage.

(B) ERRORS IN ENROLLMENT.—In the case described in section [1837\(h\)](#) (relating to errors in enrollment), in the same manner as such section applies to part B.

(C) EXCEPTIONAL CIRCUMSTANCES.—In the case of part D eligible individuals who meet such exceptional conditions (in addition to those conditions applied under paragraph (1)(B)(iii)) as the Secretary may provide.

(D) MEDICAID COVERAGE.—In the case of an individual (as determined by the Secretary) who is a full-benefit dual eligible individual (as defined in section [1935\(c\)\(6\)](#)).

(E) DISCONTINUANCE OF MA-PD ELECTION DURING FIRST YEAR OF ELIGIBILITY.—In the case of a part D eligible individual who discontinues enrollment in an MA-PD plan under the second sentence of section [1851\(e\)\(4\)](#) at the time of the election of coverage under such sentence under the original Medicare fee-for-service program.

(4) INFORMATION TO FACILITATE ENROLLMENT.—

(A) IN GENERAL.—Notwithstanding any other provision of law but subject to subparagraph (B), the Secretary may provide to each PDP sponsor and MA organization such identifying information about part D eligible individuals as the Secretary determines to be necessary to facilitate efficient marketing of prescription drug plans and MA-PD plans to such individuals and enrollment of such individuals in such plans.

(B) LIMITATION.—

(i) PROVISION OF INFORMATION.—The Secretary may provide the information under subparagraph (A) only to the extent necessary to carry out such subparagraph.

(ii) USE OF INFORMATION.—Such information provided by the Secretary to a PDP sponsor or an MA organization may be used by such sponsor or organization only to facilitate marketing of, and enrollment of part D eligible individuals in, prescription drug plans and MA-PD plans.

(5) REFERENCE TO ENROLLMENT PROCEDURES FOR MA-PD PLANS.— For rules applicable to enrollment, dis-enrollment, termination, and change of enrollment of part D eligible individuals in MA-PD plans, see section [1851](#).

(6) REFERENCE TO PENALTIES FOR LATE ENROLLMENT.—Section 1860D-13(b) imposes a late enrollment penalty for part D eligible individuals who—

(A) enroll in a prescription drug plan or an MA-PD plan after the initial enrollment period described in paragraph (2); and

(B) fail to maintain continuous creditable prescription drug coverage during the period of non-enrollment.

(c) PROVIDING INFORMATION TO BENEFICIARIES.—

(1) ACTIVITIES.—The Secretary shall conduct activities that are designed to broadly disseminate information to part D eligible individuals (and prospective part D eligible individuals) regarding the coverage provided under this part. Such activities shall ensure

that such information is first made available at least 30 days prior to the initial enrollment period described in subsection (b)(2)(A).

(2) REQUIREMENTS.—The activities described in paragraph (1) shall—

(A) be similar to the activities performed by the Secretary under section [1851\(d\)](#), including dissemination (including through the toll-free telephone number 1-800-MEDICARE) of comparative information for prescription drug plans and MA-PD plans; and

(B) be coordinated with the activities performed by the Secretary under such section and under section [1804](#).

(3) COMPARATIVE INFORMATION.—

(A) IN GENERAL.—Subject to subparagraph (B), the comparative information referred to in paragraph (2)(A) shall include a comparison of the following with respect to qualified prescription drug coverage:

(i) BENEFITS.—The benefits provided under the plan.

(ii) MONTHLY BENEFICIARY PREMIUM.—The monthly beneficiary premium under the plan.

(iii) QUALITY AND PERFORMANCE.—The quality and performance under the plan.

(iv) BENEFICIARY COST-SHARING.—The cost-sharing required of part D eligible individuals under the plan.

(v) CONSUMER SATISFACTION SURVEYS.—The results of consumer satisfaction surveys regarding the plan conducted pursuant to section 1860D-4(d).

(B) EXCEPTION FOR UNAVAILABILITY OF INFORMATION.—The Secretary is not required to provide comparative information under clauses (iii) and (v) of subparagraph (A) with respect to a plan—

(i) for the first plan year in which it is offered; and

(ii) for the next plan year if it is impracticable or the information is otherwise unavailable.

(4) INFORMATION ON LATE ENROLLMENT PENALTY.—The information disseminated under paragraph (1) shall include information concerning the methodology for determining the late enrollment penalty under section 1860D-13(b).

- SEC. 1860D-3. [42 U.S.C. 1395w-103]

*(a) ASSURING ACCESS TO A CHOICE OF COVERAGE.—*

(1) CHOICE OF AT LEAST TWO PLANS IN EACH AREA.—The Secretary shall ensure that each part D eligible individual has available, consistent with paragraph (2), a choice of enrollment in at least 2 qualifying plans (as defined in paragraph (3)) in the area in which the individual resides, at least one of which is a prescription drug plan. In any such case in which such plans are not available, the part D eligible individual shall be given the opportunity to enroll in a fallback prescription drug plan.

(2) REQUIREMENT FOR DIFFERENT PLAN SPONSORS.—The requirement in paragraph (1) is not satisfied with respect to an area if only one entity offers all the qualifying plans in the area.

(3) QUALIFYING PLAN DEFINED.—For purposes of this section, the term “qualifying plan” means—

- (A) a prescription drug plan; or
- (B) an MA-PD plan described in section [1851\(a\)\(2\)\(A\)\(i\)](#) that provides—
  - (i) basic prescription drug coverage; or
  - (ii) qualified prescription drug coverage that provides supplemental prescription drug coverage so long as there is no MA monthly supplemental beneficiary premium applied under the plan, due to the application of a credit against such premium of a rebate under section [1854\(b\)\(1\)\(C\)](#).

*(b) FLEXIBILITY IN RISK ASSUMED AND APPLICATION OF FALLBACK PLAN.—In order to ensure access pursuant to subsection (a) in an area—*

- (1) The Secretary may approve limited risk plans under section 1860D-11(f) for the area; and
- (2) only if such access is still not provided in the area after applying paragraph (1), the Secretary shall provide for the offering of a fallback prescription drug plan for that area under section 1860D-11(g).

### **Social Security Act §1802 - Free Choice by Patient Guaranteed**

- SEC. 1802. [42 U.S.C. 1395a]

**(a) BASIC FREEDOM OF CHOICE.—**

Any individual entitled to insurance benefits under this title may obtain health services from any institution, agency, or person qualified to participate under this title if such institution, agency, or person undertakes to provide him such services.

**(b) USE OF PRIVATE CONTRACTS BY MEDICARE BENEFICIARIES.—**

- (1) **IN GENERAL.—**Subject to the provisions of this subsection, nothing in this title shall prohibit a physician or practitioner from entering into a private contract with a Medicare beneficiary for any item or service—
  - (A) for which no claim for payment is to be submitted under this title, and
  - (B) for which the physician or practitioner receives—
    - (i) no reimbursement under this title directly or on a capitated basis, and
    - (ii) receives no amount for such item or service from an organization which receives reimbursement for such item or service under this title directly or on a capitated basis.

(2) **BENEFICIARY PROTECTIONS.—**

- (A) **IN GENERAL.—**Paragraph (1) shall not apply to any contract unless—
  - (i) the contract is in writing and is signed by the Medicare beneficiary before any item or service is provided pursuant to the contract;
  - (ii) the contract contains the items described in subparagraph (B); and
  - (iii) the contract is not entered into at a time when the Medicare beneficiary is facing an emergency or urgent health care situation.

(B) **ITEMS REQUIRED TO BE INCLUDED IN CONTRACT.—**Any contract to provide items and services to which paragraph

- (1) applies shall clearly indicate to the Medicare beneficiary that by signing such contract the beneficiary—

- (i) agrees not to submit a claim (or to request that the physician or practitioner submit a claim) under this title for such items or services even if such items or services are otherwise covered by this title;
- (ii) agrees to be responsible, whether through insurance or otherwise, for payment of such items or services and understands that no reimbursement will be provided under this title for such items or services;
- (iii) acknowledges that no limits under this title (including the limits under section [1848\(g\)](#)) apply to amounts that may be charged for such items or services;
- (iv) acknowledges that Medigap plans under section [1882](#) do not, and other supplemental insurance plans may elect not to, make payments for such items and services because payment is not made under this title; and
- (v) acknowledges that the Medicare beneficiary has the right to have such items or services provided by other physicians or practitioners for whom payment would be made under this title.

Such contract shall also clearly indicate whether the physician or practitioner is excluded from participation under the Medicare program under section [1128](#).

**(3) PHYSICIAN OR PRACTITIONER REQUIREMENTS.—**

**(A) IN GENERAL.—**Paragraph (1) shall not apply to any contract entered into by a physician or practitioner unless an affidavit described in subparagraph (B) is in effect during the period any item or service is to be provided pursuant to the contract.

**(B) AFFIDAVIT.—**An affidavit is described in this subparagraph if—

- (i) the affidavit identifies the physician or practitioner and is in writing and is signed by the physician or practitioner;
- (ii) the affidavit provides that the physician or practitioner will not submit any claim under this title for any item or service provided to any Medicare beneficiary (and will not receive any reimbursement or amount described in paragraph (1)(B) for any such item or service) during the 2-year period beginning on the date the affidavit is signed; and
- (iii) a copy of the affidavit is filed with the Secretary no later than 10 days after the first contract to which such affidavit applies is entered into.

**(C) ENFORCEMENT.—**If a physician or practitioner signing an affidavit under subparagraph (B) knowingly and willfully submits a claim under this title for any item or service provided during the 2-year period described in subparagraph (B)(ii) (or receives any reimbursement or amount described in paragraph (1)(B) for any such item or service) with respect to such affidavit—

- (i) this subsection shall not apply with respect to any items and services provided by the physician or practitioner pursuant to any contract on and after the date of such submission and before the end of such period; and
- (ii) no payment shall be made under this title for any item or service furnished by the physician or practitioner during the period described in clause (i) (and no reimbursement or payment of any amount described in paragraph (1)(B) shall be made for any such item or service).

**(4) LIMITATION ON ACTUAL CHARGE AND CLAIM SUBMISSION REQUIREMENT NOT APPLICABLE.—**Section [1848\(g\)](#) shall not apply with respect to any item or service provided to a Medicare beneficiary under a contract described in paragraph (1).

**(5) DEFINITIONS.—**In this subsection:

(A) **MEDICARE BENEFICIARY.**—The term “Medicare beneficiary” means an individual who is entitled to benefits under part A or enrolled under part B.

(B) **PHYSICIAN.**—The term “physician” has the meaning given such term by paragraphs (1), (2), (3), and (4) of section [1861\(r\)](#)<sup>[3]</sup>.

(C) **PRACTITIONER.**—The term “practitioner” has the meaning given such term by section [1842\(b\)\(18\)\(C\)](#).

## **Social Security Act §1902 - State Plans for Medical Assistance**

(a) A STATE PLAN FOR MEDICAL ASSISTANCE MUST –

(23) provide that (A) any individual eligible for medical assistance (including drugs) may obtain such assistance from any institution, agency, community pharmacy, or person, qualified to perform the service or services required (including an organization which provides such services, or arranges for their availability, on a prepayment basis), who undertakes to provide him such services, and (B) an enrollment of an individual eligible for medical assistance in a primary care case-management system (described in section [1915\(b\)\(1\)](#)), a Medicaid managed care organization, or a similar entity shall not restrict the choice of the qualified person from whom the individual may receive services under section [1905\(a\)\(4\)\(C\)](#), except as provided in subsection (g), in section [1915](#), and in section [1932\(a\)](#), except that this paragraph shall not apply in the case of Puerto Rico, the Virgin Islands, and Guam, and except that nothing in this paragraph shall be construed as requiring a State to provide medical assistance for such services furnished by a person or entity convicted of a felony under Federal or State law for an offense which the State agency determines is inconsistent with the best interests of beneficiaries under the State plan.

## **CFR §483.60 Pharmacy Services**

The nursing home must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in [§483.75\(h\)](#) of this part. The nursing home may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

### ➤ Interpretive Guidelines §483.60

- The nursing home is responsible under [§483.75\(h\)](#) for the “timeliness of the services.”
- A drug, whether prescribed on a routine, emergency, or as needed basis, must be provided in a timely manner.
- If failure to provide a prescribed drug in a timely manner causes the resident discomfort or endangers his or her health and safety, then this requirement is not met.

### ➤ Procedures §483.60

- During the surveyor’s observation of the drug pass, are all ordered medications available?

### ➤ Procedures §483.60(a)

- A nursing home must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.