MEDICARE PRESCRIPTION DRUG COVERAGE TRAININGS FOR AMERICAN INDIANS/ALASKA NATIVES

AWARENESS TRAINING TOOL KIT
TABLE OF CONTENTS

Training Materials
IHS and CMS Combined Materials

SOCIAL SECURITY ADMINISTRATION (SSA)

Awareness Training on Medicare Prescription Drug Coverage

Agenda

Morning

8:30 - 8:45 - Introduction and Opening Prayer - IHS staff

8:45 - 9:00 - Overview of TTAG and TTAG Resources - TTAG member or representative

9:00 - 10:30 - Overview of Medicare Prescription Drug Coverage (key messages, eligibility and enrollment, limited income provisions, drug coverage, coordination with other coverage) - CMS Staff

10:30 - 10:45 - Break

10:45 - 11:30 - SSA Role in Drug Coverage Implementation - Extra Help paying for prescription drugs (timeline for implementation and enrollee communication, application and approval process, SSA outreach activities, and coordination with Tribes) - SSA staff

11:30 - 12:00 - Questions and Answers - CMS, IHS and SSA staff

12:00 - 1:00 - Lunch

Afternoon

1:00 - 3:00 - Panel and Presentations - Planning and Conducting Outreach and Education and specialty areas such as pharmacy contracts, further information on SSA outreach, coordination with State Medicaid Offices, other counseling and information resources and additional topics as determined by Area Office - IHS staff, CMS Staff, SSA staff, State Medicaid staff, and State Health Insurance Counseling Program staff
*additional topics to be determined

3:00 - 3:15 - Break

3:15 - 4:30 - Recap Summary, Final Questions and process to get back with answers, Resources for ongoing information, Next steps, Evaluation - IHS and CMS staff

Note to IHS Coordinators – Please record all "unanswered or open questions" and forward them to Rodger Goodacre – rodger.goodacre@cms.hhs.gov and Balerma.Burgess@mail.ihs.gov

MEDICARE PRESCRIPTION DRUG COVERAGE
AWARENESS TRAININGS FOR AMERICAN INDIANS/ALASKA NATIVES
TRAINING DATES

DATES	*CMS REGION*	*IHS AREA*	*LOCATION*
May 17	Dallas	Albuquerque	Santa Ana Star Casino 54 Jemez Canyon Cam Rd Santa Ana Pueblo Bernalillo NM 87004 505-867-0000
May 24	Dallas and Kansas City	Oklahoma	Reed Center 5800 Will Rogers Rd Midwest City OK 73110
May 25	Denver	Billings	Billings Hotel and Convention Ctr Billings, MT
May 27	San Francisco and Dallas	Navajo	Navajo Nation Museum Window Rock AZ 86515 928-871-6675
June 2	Chicago	Bemidji	The Hagerty Center 1701 E. Front St. Traverse City, MI 49686
June 2	Denver and Kansas City	Aberdeen	Ramkota Best Western Hotel and Convention Center 1400 8th Ave. Aberdeen SD 57401 605-229-4040
June 7	San Francisco	Sacramento	IHS Area Office Sacramento CA
June 8	Seattle	Alaska	Anchorage AK
June 16	Seattle	Portland	Seattle RO Training Center Seattle WA
June 16	San Francisco	Phoenix &Tucson	Phoenix Area Office 6th Floor Conference Room Phoenix, AZ
June 20	Boston, New York and Atlanta	Nashville	Nashville - TBD

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5/27/2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Indian Health Service
Rockville MD 20852

APR 29 2005

Dear Tribal Leader:

The purpose of this letter is to inform Tribes, Tribal organizations, and Urban Indian programs (T/Us) of activities essential to successful implementation of the Medicare Prescription Drug Benefit (Medicare Part D). This permanent drug benefit authorized in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, begins January 1, 2006, with the expiration of the Medicare Prescription Drug Discount Card and the Transitional Assistance program. This drug benefit will provide a new resource for Medicare beneficiaries who may not have had coverage to receive drugs through enrollment in a Medicare Prescription Drug Plan (PDP) or Medicare Advantage Plan (MA-PD), otherwise known as "Medicare Part D" plans. The IHS Medicare beneficiaries who receive drug coverage through Medicaid will be required to convert to the Medicare Prescription Drug Benefit. To receive reimbursement, the Indian Health Service (IHS), Tribes, Tribal organizations, and Urban Indian programs (I/T/Us) will be required to bill the various Medicare Part D plans that enroll our patients.

You will need to be aware of the following items as you start to prepare for the Medicare Prescription Drug Benefit:

1. Billing – To be able to bill for pharmaceuticals, sites will need a seven-digit National Council for Prescription Drug Programs (NCPDP) or an Alternate Site Enumeration Program (ASEP) number. The NCPDP number is a unique identifier for pharmacies to use when they bill third-party payers for pharmaceuticals. The ASEP number is an identifier for sites without a pharmacy where prescribers dispense medications. These sites are also known as dispensaries. Information about the NCPDP and ASEP programs is available at http://www.ncpdp.org/main_frame.htm. Once at this Web site, click on "NCPDP Provider ID." While almost all T/U pharmacies have an NCPDP number, very few sites without pharmacies have an ASEP number. Either an NCPDP or an ASEP number will be needed when T/U sites sign contracts or billing agreements with Medicare Part D plans.

   Medicare Part D plans do not have a listing of T/U dispensaries and will not send contracts or agreements to them unless the T/U dispensaries contact the individual plan directly or provide contact information to IHS Headquarters. The dispensaries can send their contact name, address, phone number, and e-mail address to CAPT Robert Pittman, IHS Principal Pharmacy Consultant, IHS Headquarters, to be added to the list of I/T/U pharmacies that will be made available to the Part D plans.

2. Training – The IHS and Centers for Medicare and Medicaid Services (CMS) are planning two training sessions per IHS Area on the Medicare Prescription Drug Benefit. The first training session for each Area is scheduled for May or June 2005 (see Attachment A –

Training Information). The T/Us will need to work with the Area Office point of contact to ensure that appropriate individuals (e.g., from patient registration, the billing office, and the pharmacy) at each site attend these training sessions. The second training for each Area is expected to take place in September 2005.

3. Contracting – Current Medicaid beneficiaries who are eligible for Medicare will have their prescription drug coverage changed from Medicaid to a Medicare PDP or an MA-PD starting on January 1, 2006. The I/T/Us will need to have contracts or agreements in place with Medicare Part D plans to be able to bill for medications dispensed to Medicare beneficiaries. The IHS, the CMS, Tribal Technical Advisory Group (TTAG), and Tribal consultants developed IHS-specific and T/U-program-specific addenda for Part D plans to use when developing contracts or agreements for I/T/U pharmacies and dispensaries (see Attachment B – Current Status of Part D Implementation and Attachment C – T/U program addendum).

   The I/T/Us may receive up to 40 contracts or agreements from the Part D plans asking I/T/U pharmacies to participate in the plans' pharmacy network. The T/Us will need to review these contracts or agreements, negotiate any needed changes, and have contracts or agreements in place by early summer 2005 (most plans will ask for a 45-day turn around time). The T/Us will need to review the contracts to determine if the addendum issues are addressed, if the proposed reimbursement rate is acceptable, and if there are any T/U-specific issues they wish addressed.

   The IHS direct care sites have been asked not to proceed with the contracting process but to report plan contact information to CAPT Pittman. A contract or agreement addendum specific to IHS direct care sites has been developed (go to http://www.cms.hhs.gov/pdps/ihsaddendum021605.pdf). The IHS Headquarters staff will review plan contracts or agreements for all IHS direct sites, negotiate changes as needed, and complete the contracting process.

4. Outreach and Education – The T/Us are encouraged to develop outreach and education plans, programs, and materials to inform staff and beneficiaries about the Medicare Prescription Drug Benefit and the process for completing the Low Income Subsidy (LIS) Application (to be mailed to beneficiaries by the Social Security Administration in May 2005). The LIS will assist individuals with premium payments, deductions, and cost share payments. Each IHS Area Office and CMS staff will be available to assist in this process.

5. The CMS Web site – The CMS Tribal Government Information Web site will provide periodic updates about the Medicare Prescription Drug Benefit for Tribal Leaders. Tribal Leaders and Urban Program Directors are encouraged to visit the CMS Web site frequently at http://www.cms.hhs.gov/medicarereform/pdbma/tribal.asp.

Additional information and materials are enclosed providing basic information about the Medicare Prescription Drug Benefit (see Attachment D). If you have questions about this program, please contact your Area Office point of contact, or contact CAPT Pittman at (301) 443-1190 or Robert.pittman@ihs.gov.

Sincerely yours,

Charles W. Grim, DDS

Charles W. Grim, D.D.S., M.H.S.A.
Assistant Surgeon General
Director

Enclosures

Attachment A- Medicare Part D Training Information
Attachment B- Current Status of Part D Implementation
Attachment C- T/U Program Addendum
Attachment D- Summary of Medicare Prescription Drug Benefit

IMPLEMENTATION OF MEDICARE PRESCRIPTION DRUG COVERAGE
AWARENESS TRAININGS FOR AMERICAN INDIANS/ALASKA

BUILDING AWARENESS **PHASE ONE**

2005	CMS Centers for Medicare and Medicaid Services	SSA Social Security Administration
MAY		
	DHHS Regional Consultations ▪ **MAY 23-24** Region IX San Francisco ▪ **MAY 25-26** Region X Ocean Shores, WA AI/AN Awareness **TRAININGS** IHS Area Offices[1] ▪ **MAY 17** Albuquerque ▪ **MAY 24** Oklahoma ▪ **MAY 25** Billings ▪ **MAY 27** Navajo ▪ CMS **MAILS** "You will automatically receive extra help" notice to most people with Medicare and Medicaid full benefits and those with Medicare Savings Programs (MSP) - Qualified Medicare Beneficiaries (QMB), Specified Low-Income Medicare Beneficiary (SLMB), or Qualifying Individual (QI). ▪ Prescription drug plans (PDP) send contracts to Indian Health Service (IHS) Headquarters, Tribes, and Urban Indian Health Program pharmacies.	▪ SSA **MAILS** letter and application to people with limited incomes who may qualify for extra help. ▪ Online information and applications available on line http://www.socialsecurity.gov/
JUNE	**CMS**	
	DHHS Regional Consultations **JUNE 8-9** Region VIII Denver, CO AI/AN Awareness Trainings IHS Area Office ▪ **JUNE 2** Bemidji -Michigan ▪ **JUNE 2** Aberdeen	

[1] Dates subject to change. Contact your IHS Area Office for final date and location of training.

5/27/2005

	▪ **JUNE 7** Sacramento ▪ **JUNE 8** Seattle- Anchorage ▪ **JUNE 16** Seattle - Portland ▪ **JUNE 16** Phoenix &Tucson ▪ **JUNE 20** Nashville ▪ **JUNE 6** Plan bids due ▪ **JUNE 7** PDPs and Medicare Health Plans with Prescription Drug Coverage may submit marketing materials to CMS for review ▪ **JUNE 30** last day for low-income people to apply for and receive the $450 credit from the Medicare Prescription Drug Discount Card ▪ CMS General Population Regional Train the Trainer Workshops begin ▪ SSA mails letters to incomplete applicants & request response	
JUNE	**CMS**	**SSA**
	▪ CMS **MAILS** of "You will automatically receive extra help"letter to people with Medicare Savings Programs (MSP), and to all SSI only recipients. ▪	▪ SSA begins processing applications for extra help and sending outcome letters.
JULY	**CMS**	**SSA**
	▪ **JULY 15** CMS finalizes PDPs and Medicare Health Plans with Prescription Drug Coverage must meet beneficiary pharmacy access standards (therefore plans will want to have all pharmacy agreements finalized by this date)	▪ SSA online application for extra help available http://www.socialsecurity.gov ▪ SSA mails pre-decisional letter stating that the applicant is not eligible to incomplete applicants that have still not responded. They have 10 days to respond to this letter ▪ If no response, SSA sends denial letter giving applicant 60 days to appeal decision
AUGUST	**CMS**	**SSA**
	▪ Plans must submit to CMS current status of agreements with I/T/U pharmacies and dispensaries.	▪ SSA mails decisions to applicants with limited incomes requesting extra help ▪ SSA mails application to non-deemed potential beneficiaries with limited incomes requiring extra help.

SEPTEMBER	CMS
	▪ **DEADLINE** contracts with PDPs and Medicare Health Plans with Prescription Drug Coverage are signed. CMS announces PDPs and their exact premiums and lists of covered drugs. ▪ IHS Area Offices/ CMS Regional Offices will begin 2nd round of Area level Medicare Prescription Drug Coverage **TRAININGS** for I/T/U sites. ▪ Medigap notifies policy-holders whether coverage is as good as Medicare Prescription Drug Plan. ▪ Drug card sponsors send out transition letters to beneficiaries ▪ **SEPTEMBER 30** last day for low-income beneficiaries to apply for and receive the $300 credit from the Medicare Prescription Drug Discount Card
OCTOBER	**CMS**
	▪ October 1 Drug plans can begin marketing to people with Medicare. ▪ CMS **MAILS** *Medicare & You Handbook* to all beneficiaries, with drug plan information. ▪ CMS **MAILS** "You've been enrolled" notice to individuals with full Medicare and Medicaid benefits. ▪ **OCTOBER 31** "Medicare Prescription Drug Plan Finder" web WWW.MEDICARE.GOV tool becomes available to compare Medicare drug plans in each area.

DECISION **PHASE TWO**

NOVEMBER	CMS
	▪ Ongoing monthly auto-enrollment of new individuals with full Medicare and Medicaid benefits. ▪ **NOVEMBER 15** Medicare prescription drug plan enrollment begins for ALL people with Medicare (open enrollment through MAY 15, 2006). ▪ Employers/Unions send information to their retirees about coverage as good as Medicare. ▪ **NOVEMBER 30 DUE** last day for low-income beneficiaries to apply for and receive the $150 credit from the Medicare Prescription Drug Discount Card
DECEMBER	**CMS**

	▪ **DECEMBER 31** people with both Medicare and Medicaid full benefits will be enrolled in a Medicare prescription drug plan automatically if they have not already chosen one. ▪ **DECEMBER 31** Medicaid drug coverage ends for people with both Medicare and Medicaid full benefits.	▪ SSA begins premium withhold from beneficiary checks.
2006		
JANUARY	**CMS**	
	▪ **JANUARY 1 Drug Benefit begins for beneficiaries who enrolled by December 31, 2005** ▪ Individuals with Medicare and Medicaid full benefits can change plan monthly ▪ Individuals eligible for both Medicare and Medicaid will automatically begin receiving prescription drug coverage through Medicare ▪ Open enrollment for Medicare Advantage plans ▪ Late enrollment penalty begins to accrue (except for individuals with coverage as good as Medicare)	
MAY	**CMS**	
	▪ **MAY 15 DUE** Last day to enroll in a Medicare prescription drug plan without late enrollment premium penalty ▪ CMS mails Facilitated enrollment notices to beneficiaries approved to receive extra help but who have not yet enrolled in a plan, SSI recipients and those in MSPs (QMB, SLMB or QI. **JUNE 1, 2006** enrollment for these groups takes effect ▪	

ATTACHMENT B

CURRENT STATUS OF PART D IMPLEMENTATION

In January 2006, 41 million people with Medicare, including an estimated 60,000 to 70,000 American Indian and Alaska Natives, will have the option of enrolling in a plan that covers prescription medications. These plans will be offering prescription drug coverage, which is different from discounts that were offered by the Medicare-approved drug discount cards. CMS contracts with private drug plans (PDPs) or Medicare Advantage plans (MA-PD) to negotiate discounted prices on behalf of their enrollees. Insurance companies and other appropriate organizations bid to serve as prescription drug plans. The IHS, the CMS Tribal Technical Advisory Group (TTAG) and CMS staff worked to make sure the final regulations for Medicare Part D took into account health care services in Indian country. The final regulations for Medicare Part D were published by CMS on January 28, 2005 (available at http://www.cms.hhs.gov/medicarereform/).

As part of the preparation process, IHS, TTAG and CMS staff felt there was a need to provide guidance to prospective plans about applicable laws, and regulations that would potentially impact the contracting process with Tribes and Urban programs. To that end, the IHS, TTAG and CMS staff developed a Tribal/Urban program addendum for Part D plans to use when creating their contracts or agreements for T/U pharmacies and dispensaries (see Attachment C). Plans have reviewed this document, developed their pharmacy contracts or agreements and have submitted their proposed contracts to CMS for review and approval. Plans are expected to submit contracts or agreement to T/U pharmacies throughout April and May 2005. Some Tribal sites have already reported receiving Part D plan contracts or agreements. Pharmacists working at Tribal or Urban programs, have been asked to contact the Tribe or hospital or clinic Chief Executive Officer to determine who is the appropriate individual to review and negotiate contracts or agreements for the Tribe or Urban program. Some sites may receive 20 or more contracts or agreements with short turn around times.

Pharmacists at IHS direct care sites have been asked not to proceed with the contracting process but to report plan contact information to CAPT Robert Pittman, Principal Pharmacy Consultant. A contract or agreement addendum specific to IHS direct care sites has been developed (go to http://www.cms.hhs.gov/pdps/ihsaddendum021605.pdf) The IHS Headquarters staff will review plan contracts or agreements for all IHS direct sites, negotiate changes as needed and complete the contracting process.

The IHS, TTAG and CMS staffs have been developing Outreach and Education training programs to train I/T/U sites about the Medicare Part D Prescription Drug Benefit. Two in person trainings will take place in each IHS Area in 2005. The first trainings will take place in May 2005 and will educate staff about the benefit, the contracting process, how to assist beneficiaries in completing the Social Security Low Income Subsidy paperwork and how sites can prepare for outreach and education efforts for their local beneficiaries. A second training will take place in each IHS area in September 2005. This training will provide a final update on approved plans, give additional information about auto enrollment of dual eligible beneficiaries and provide an update on claims processing using the IHS Point of Sale billing package. In addition to the formal training sessions, IHS and CMS plan 3 or 4 nationwide conference calls to provide updates and allow Service Unit staff the opportunity to ask questions and bring up issues. A question and answer sections will be added to both the IHS and CMS Medicare websites where Tribes and staff can go to see questions and answers from the conference calls and from staff who have contacted IHS headquarters or CMS.

Information for Part D Sponsors on Contracting With Indian Health Care Providers

OVERVIEW

All Part D sponsors are required to offer network contracts to all Indian Health Service, Tribes or Urban Indian program (I/T/U) pharmacies operating in the sponsor's service area. These contracts must include standard terms and conditions that conform to a model contract addendum to be provided by CMS in February, 2005. The model addendum will account for differences in the operations of I/T/U pharmacies and retail pharmacies. The following provides background information on I/T/U services that will be useful to Part D sponsors as they carry out these requirements.

The Indian Health Service (IHS), an agency within the Department of Health and Human Services, is responsible for providing health services to descendants of federally recognized American Indians and Alaska Natives (AI/ANs). The provision of health services to AI/ANs is based on the unique government-to-government relationship between tribes and the Federal Government established by treaties, court decisions, and federal statutes. Generally, AI/ANs are not charged for medical services or pharmaceuticals provided and any co-payments and deductibles are waived for services.
The IHS is the principal Federal health care provider for AI/ANs and serves as an advocate for Indian health. The mission of the IHS is to raise the health status of AI/ANs to the highest possible level.

The IHS is the primary source of health services for 55% of the estimated 2.4 million AI/ANs from more than 560 federally recognized tribes in 35 States. The IHS has a total of 88,000 Medicare beneficiaries of which approximately 30,500 are dually eligible for Medicare and Medicaid. The majority of Indian people served by IHS live on or near reservations in some of the most remote and poverty stricken areas of the country where other sources of health care are less available. Health care services are provided to AI/ANs through IHS-operated facilities, through funding agreements with Tribes or Tribal organizations pursuant to the Indian Self-Determination and Education Assistance Act, (ISDEA), and through contracts with 34 urban Indian organizations. Urban Indian health programs provide limited services to more than 150,000 Indians living in 34 cities. Five urban programs provide pharmaceutical services through in-house pharmacies. The Indian health care providers are often referred to as I/T/U programs (operated by IHS, operated by Tribes, or operated by urban programs). For many AI/ANs, the I/T/U program is the only accessible source of health care, given travel, language and cultural barriers.

HEALTH CARE FACILITIES

The IHS is organized as 12 "area offices" which are located throughout the United States. Within the 12 areas are 594 health care delivery facilities, including 48 hospitals, 232 health centers, and 314 health stations, satellite clinics, and Alaska village clinics operated by IHS and tribes. The IHS provides direct health care services at 35 hospitals

and 111 ambulatory facilities. At 13 hospitals and 435 ambulatory facilities, Tribes or Tribal organizations contract or compact under the ISDEA and have assumed operation of the delivery of health care services previously carried out by the IHS. Over one-half of the IHS resources are administered by Tribes or Tribal organizations operating health programs pursuant to the ISDEA.

PHARMACIES

There are a total of 235 pharmacies in the I/T/U system (see Attachment A for a complete list of pharmacies). Pharmacies are located in the hospitals and clinics and are operated differently than most private sector retail pharmacies. Pharmacies may have higher operating costs due to the practice model used by IHS. IHS tends to use more pharmacists and fewer technicians than the private sector pharmacies since the patient's medical record is reviewed prior to filling prescriptions and the patient receives patient counseling in private counseling room for both new and refill medications. Pharmacists at many sites run pharmacy specialty clinics following patients with specific disease states.

State	# of I/T/U Pharmacies	PDP Region#	MA PPO Region #
Alabama	1	12	10
Alaska	15	34	26
Arizona	23	28	21
California	18	32	24
Colorado	2	27	20
Connecticut	1	2	2
Idaho	3	31	23
Kansas	5	24	18
Maine	3	1	1
Michigan	7	13	11
Minnesota	7	25	19
Mississippi	1	20	16
Montana	13	25	19
North Carolina	1	8	7
North Dakota	5	25	19
Nebraska	3	25	19
New Mexico	23	26	22
New York	3	3	3
Oklahoma	43	23	18
Oregon	7	30	23
South Dakota	12	25	19
Texas	2	22	17
Utah	1	31	23
Washington	12	30	23
Wisconsin	11	16	14
Wyoming	2	25	9

ACQUISITION OF PHARMACEUTICALS

The Department of Veterans Affairs (VA) provides Indian Health Service (IHS) and Tribes use of the VA Pharmaceutical Prime Vendor (PPV) for purchasing pharmaceuticals at discounted prices. By ordering through the VA PPV, IHS and Tribes are able to access Federal Supply Schedule (FSS) Contract, National Standardization Contract (NSC) and Blanket Purchase Agreement (BPA) pricing for pharmaceuticals.

In addition to accessing medications from the VA PPV, Tribes and Urban programs qualify as Federally Qualified Health Centers and after approval of the Health Resources and Services Administration Office of Pharmacy Affairs, are eligible to order medications at 340B Drug Pricing.

Because IHS acquires drugs through federal supply sources, this may impact a Medicare Part D sponsor's ability to negotiate rebates from manufacturers for these medications purchased by the I/T/U and dispensed to the plan members.

FORMULARIES

All I/T/U facilities have their own local formularies. Two IHS areas, Aberdeen and Oklahoma City, have area-wide formularies to which sites can add additional medications. The IHS also has a National Core Formulary of medications which must be available at all IHS sites. Since most I/T/U patients see a health care provider at the I/T/U hospital or clinic and also get their medication at the same facility, the vast majority of prescribed medications are on that facility's local formulary. All facilities have non-formulary procedures in place to be able to provide patients with needed medications that are not on the local formulary.

APPROACHES TO SUCCESSFUL CONTRACTING WITH IHS, TRIBAL AND URBAN PROGRAMS

Medicare Part D Sponsors are required to offer contracts to all I/T/U pharmacies and dispensaries. Because of their unique status under Federal law, Part D Plan Sponsor will find the IHS or Tribal addendum helpful as models for an addendum to its standard pharmacy network agreement in order to contract with these pharmacies. Furthermore, some I/T/U pharmacies do not have the same point of sale capabilities typically found in commercial retail pharmacies. The addenda will allow this rather than require the I/T/U pharmacies to convert to different technologies; plans will need to work around this, including batch processing or processing paper claims routinely in the case of a few pharmacies and dispensaries. CMS will post suggested texts for these addenda on its website. All Part D Plan Sponsors are expected to model their addenda on these suggested texts and must offer them to all Indian health pharmacies in the PDP regions in

which the Sponsors will operate. The addenda to be used by each Part D Plan Sponsor must be submitted to CMS. Two addenda will be required:

- The Indian Health Service will execute a master agreement + addenda (that can vary by state) with Part D Plan Sponsors to cover all the pharmacies and dispensaries I HS operates directly.
- An Indian tribe, tribal organization or urban Indian organization which operates one/more pharmacies or dispensaries must execute an individual pharmacy network agreement + addendum with Part D Plan Sponsors.

Multi-tribal agreements. Indian tribes/tribal organizations in some areas of the country may wish to negotiate pharmacy network agreements + addendum as a group to make the process more efficient. Part D Plan Sponsors are encouraged to contact the IHS Area Health Boards to identify tribes and tribal organizations with an interest in negotiating a group agreement. *A list of IHS Area Health Boards is available at <www.nihb.org>; click on "Area Health Boards".* Each tribe or tribal organization participating in the group would execute an agreement + addendum with the Part D Plan Sponsor.

Web resources. CMS and IHS will establish web access to information on network contracting resources with I/T/Us. Information expected to be posted includes: the CMS model addenda (one for IHS; one for tribes, tribal organizations and urban Indian organizations); contact personnel at IHS Area Health Boards; contact personnel at individual tribal and urban programs; and, on a voluntary basis if plans so desire, network pharmacy agreements/ addenda developed by Part D Plan Sponsors. Sponsors interested in this opportunity should provide a copy of their materials to the following for posting on the website:

CAPT Robert E. Pittman
Principal Pharmacy Consultant
Indian Health Service
801 Thompson Ave., Room 319
Rockville, MD 20852
Phone: 301-443-1190
E-mail: rpittman@na.ihs.gov

REIMBURSEMENT FOR INDIAN HEALTH PHARMACIES

IHS patients do not pay for health services received at I/T/U facilities. Pharmaceuticals provided to patients by I/T/Us or paid for by contract health services will satisfy the plan deductible under the Part D benefit. However, pharmaceutical costs paid by I/T/U pharmacies will not count toward a beneficiary's "true" out-of-pocket limit, after which the beneficiary receives catastrophic coverage. (In contrast, drug costs paid by CMS for individuals eligible for the low-income subsidy under Part D, including the cost of covered drugs obtained at I/T/U pharmacies, will count toward the true out-of-pocket limit.) IHS patients who do not qualify for the low income subsidy under Part D are not

expected to be able to reach the catastrophic limit. [*Note: the low-income subsidy is not only available to full-benefit dually eligible individuals, but also other low-income individuals.*] This would limit the Sponsor's annual claims payment liability for each AI/AN enrollee to $1500.

CMS's model addenda for network pharmacy agreements with IHS, tribe/tribal organization and urban Indian organization pharmacies provide that a Part D Plan Sponsor pay the pharmacy's claims at rates that are reasonable and appropriate to cover their costs. In the Medicare-approved Prescription Drug Discount Card Program, the two sponsors who received CMS' approval to administer the transitional assistance credit at these pharmacies used the applicable States' Medicaid reimbursement rates (AWP-X%, plus dispensing fee). While Part D sponsors are not required to contract for these rates, Attachment B is provided as a reference for the types of rates under which I/T/U pharmacies presently contract.

CONTRACTING GUIDE FOR
TRIBAL AND URBAN INDIAN ORGANIZATION PHARMACIES
REGARDING THE MEDICARE PRESCRIPTION DRUG BENEFIT

Introduction and Purpose of this Contracting Guide

The purpose of this Contracting Guide is to provide information to pharmacies and dispensaries[1] operated by tribes, tribal organizations and urban Indian organizations for participation in the Medicare prescription drug benefit established by the Medicare Modernization Act (MMA). This drug benefit will begin January 1, 2006. (For contracting with IHS facilities a separate addendum is available and must be used).

The program operates through Medicare approved prescription drug plans (PDPs) which will make drugs available to Medicare beneficiaries who enroll in the plan.

A provision of the MMA establishes a special mechanism for pharmacies operated by IHS, tribes/tribal organizations, and urban Indian organizations (I/T/Us) to participate in the networks of prescription drug plans and receive reimbursement for prescriptions provided to plan beneficiaries.

Contracting with Prescription Drug Plans

In order to participate in a prescription drug program's network each tribal and urban Indian organization must establish a contractual relationship with the plan.[2] A pharmacy will not be able to participate in the program or bill the PDP for dispensed drugs without a contract in place. To help facilitate the contracting process for tribal and urban pharmacies, the Tribal Technical Advisory Group[3] identified legal principles specific to tribal and urban (T/U) pharmacies, and developed a contract addendum that reflects those principles. Plans are expected to use their standard pharmacy contract and attach the T/U addendum or to incorporate the T/U addendum items into a new contract. The contracts will be mailed to the chief pharmacist at each T/U pharmacy and that individual will be responsible for forwarding the contract to the appropriate contracting official for the Tribe or Urban program. The contracting official and legal counsel should review the contract to assure that all the T/U Addendum issues are addressed and specifically look at issues which might affect Tribal sovereignty and reimbursement. The T/U will have 45 days from the date of receipt of the contract to sign, negotiate changes or reject the contract. It is recommended that if the T/U expects the review process will take more than 45 days, they immediately contact the plan in writing and request a written extension. **Plans may grant additional time, but are not required to do so.** If a plan's contract does not contain all of the provisions of the T/U addendum or if the T/U addendum items have been modified to change the intent, the tribal or urban Indian program should notify the IHS identifying the specific plan and the issue. Please contact CAPT Robert Pittman at (301) 443-1190 or by E-mail at Robert.pittman@ihs.gov . If

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[1] Both pharmacies and dispensaries are eligible to participate in this program. For convenience, this Guide refers to pharmacies, only, but the use of that term should be read to include dispensaries, also.

[2] The Indian Health Service must also enter into contractual arrangements with the I/T/U endorsed plans in order for IHS direct-operated pharmacies to participate. IHS will do this through a master contract with each plan. The IHS master contract arrangements are not described here.

[3] The Tribal Technical Advisory Group (TTAG), established by the Centers for Medicare and Medicaid Services (CMS) in 2004, is comprised of tribal leaders or tribal employees appointed from each IHS Area and 3 tribal health organizations. Its role is to advise CMS on Indian Medicare, Medicaid and SCHIP issues. The NIHB's Medicare/Medicaid Policy Committee provides technical support to the TTAG.

the issue involves one of the terms of the T/U addendum, CAPT Pittman will notify CMS of the issue and CMS will work with the plan to assure compliance with the T/U addendum. For those provisions of the contract that are not covered by the T/U addendum, the T/U should negotiate directly with the plan. Examples of such provisions are reimbursement rate and formulary issues.

There is no limit on the number of plan networks a pharmacy may join. It is recommended that all tribal and urban Indian pharmacies join the networks of several plans since it will not be known until September which plans will be available to dual eligible beneficiaries (those with both Medicare and Medicaid).

Pharmacy products and billing rates

CMS regulations recognize that I/T/U pharmacies may acquire drugs from the FSS or 340B drug programs. Therefore, plan contracts should not require an I/T/U pharmacy to purchase drugs from the plan.

In the contracting guide to PDPs, the State Medicaid Payment rates were provided. However, plans can propose payment rates that are different from that used in the Medicare Prescription Drug Discount Card contracts. Each contract will need to be reviewed to determine appropriateness of reimbursement.

Claims processing

Electronic claims. Most I/T/U pharmacies have electronic billing capabilities and therefore can bill the plan though that method and have their claims immediately processed. Individual sites will need to determine if they can comply with the electronic claims processing requirements.

Non-electronic claims. Locations without electronic billing capabilities may file paper claims. If your site does not have electronic billing capabilities, please make sure the contract addresses how your paper claims will be processed.

Contracting Questions

Carol Barbero (Hobbs, Straus law firm) and Myra Munson (Sonosky, Chambers law firm) are available to give advice about the sample contract to clients of their respective law firms. Other tribal or urban sites should seek advice from their own attorneys.

INDIAN HEALTH ADDENDUM TO

MEDICARE PART D PLAN AGREEMENT

1. Purpose and Supercession of this Indian Health Addendum

The purpose of this Indian Health Addendum is to apply special terms and conditions to the Pharmacy Agreement between the _____("the Provider") and _____ (herein "Part D Plan Sponsor") for administration of the Medicare Prescription Drug Benefit program at pharmacies and dispensaries of the IHS as authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Parts 403, 411, 417, 422 and 423 of Title 42, Code of Federal Regulations. To the extent that any provision of the Pharmacy Agreement or any other addendum thereto is inconsistent with any provision of this Indian Health Addendum, the provisions of this Indian Health Addendum shall supersede all such other provisions.

2. Definitions.

For purposes of the Pharmacy Agreement, any other addendum thereto, and this Indian Health Addendum, the following terms and definitions shall apply:

(a) The term "Part D Plan Sponsor" means a nongovernmental entity that is certified under 42 CFR 417.472, 42 CFR Part 422 and 42 CFR Part 423,as meeting the requirements and standards that apply to entities that offer prescription drug plans.

(b) The terms "Part D Plan" means a prescription drug coverage that is offered under a policy, contract or plan that has been approved as specified in 42 CFR 422.502 or 42 CFR 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the requirements under subpart K of 42 CFR 422 or subpart K of Part 423.

(c) The term "Indian Health Service" (IHS) means the agency of that name within the U.S. Department of Health and Human Services established by Sec. 601 of the Indian Health Care Improvement Act, 25 USC §1661, and all pharmacies and dispensaries operated by the IHS.

(d) The term "Centers for Medicare and Medicaid Services" means the agency of that name within the U.S. Department of Health and Human Services.

(e) The term "the Provider" means the Indian Health Service (IHS), and all pharmacies and dispensaries operated by the IHS.

(f) The term "Centers for Medicare and Medicaid Services" means the

agency of that name within the U.S. Department of Health and Human Services.

(g) The term "Indian" has the meaning given to that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(h) The term "Dispensary" means a clinic where medicine is dispensed by a prescribing provider.

3. Description of Provider.

The Provider identified in Section 1 of this Indian Health Addendum are the IHS operated Service Units, including hospitals, health centers and one or more pharmacies or dispensaries. Where IHS service units operate more than one pharmacy or dispensary all such pharmacies and dispensaries are covered by this Addendum.

4. Deductibles

The cost of pharmaceuticals provided at a pharmacy or dispensary of the Provider, or paid for by the Provider through a referral to a non-IHS retail pharmacy, shall count toward the deductible applicable to an IHS beneficiary enrolled in a Part D Plan.

5. Persons eligible for services of the Provider.

(a) The parties agree that IHS is limited to serving eligible IHS beneficiaries pursuant to Part 136 of Title 42, Code of Federal Regulations and section 813(a) of the Indian Health Care Improvement Act, [IHCIA] 25 USC §1680c (a). The Provider may provide services to non-eligible persons only under certain circumstances in section 813(b) and in emergencies under section 813(c) of the IHCIA.

(b) No clause, term or condition of the Pharmacy Agreement or any addendum thereto shall be construed to change, reduce, expand or alter the eligibility of persons for services of the Provider under the Plan that is inconsistent with the authorities identified in subsection (a).

6. Applicability of other Federal laws.

The parties acknowledge that the following Federal laws and regulations apply to the IHS:

(1) The Anti-Deficiency Act 31 U.S.C. § 1341;
(2) The Indian Self Determination and Education Assistance Act (ISDEAA); 25 USC § 450 et seq.;

(3) The Federal Tort Claims Act (FTCA), 28 U.S.C. § 2671-2680;
(4) The Federal Medical Care Recovery Act, 42 U.S.C. § 2651-2653;

(5) The Federal Privacy Act of 1974, 5 U.S.C. § 552a, 42 C.F.R. Part 2;
(6) The Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 C.F.R. Parts 160 and 164.; and
(7) The Indian Health Care Improvement Act (IHCIA), 25 U.S.C. § 1601 et seq.

7. Insurance and indemnification.

FTCA coverage available to IHS obviates the requirement that IHS carry private malpractice insurance as the United States consents to be sued in place of IHS and their employees for any damages to property or for personal injury or death caused by the negligence or wrongful act or omission of IHS and their employees acting within the scope of their employment. 28 U.S.C. § 2671-2680. Nothing in the Pharmacy Agreement shall be interpreted to authorize or obligate any IHS employee to operate outside the scope of his/her employment. The IHS shall not be required to acquire insurance, provide indemnification, or guarantee that the Plan will be held harmless.

8. Employee license.

States may not regulate the qualifications of Federal employees who are carrying out their authorized Federal activities within the scope of their employment. Consequently, the parties acknowledge that IHS employees are not subject to state licensure laws and IHS pharmacy departments are not licensed by individual states. The parties agree that during the term of the Pharmacy Agreement, IHS pharmacists are currently licensed in accordance with federal statutes and regulations, and the IHS facility is accredited in accordance with federal statutes and regulations. During the term of the Pharmacy Agreement, the parties agree to use the IHS facility's Drug Enforcement Agency (DEA) number consistent with federal law.

9. Dispute Resolution.

In the event of any dispute arising under the Participating Pharmacy Agreement or any addendum thereto, the parties agree to meet and confer in good faith to resolve any such disputes. Any dispute hereunder that cannot be resolved by and between the parties in good faith shall be submitted to the dispute resolution procedure pursuant to the Participating Pharmacy Agreement.

10. Governing Law.

The Pharmacy Agreement and all addenda thereto shall be governed and

construed in accordance with Federal law of the United States. In the event of a conflict between the Pharmacy Agreement and all addenda thereto and Federal law, Federal law shall prevail.

11. Pharmacy/Dispensary Participation.

The Pharmacy Agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider. Where pharmacies are required to use National Council for Prescription Drug Programs (NCPDP) provider number for reimbursement, dispensaries will be use NCPDP Alternate Site Enumeration Program (ASEP) numbering for reimbursement.

12. Acquisition of Pharmaceuticals.

Nothing in the Pharmacy Agreement and all addenda thereto shall affect the Provider's acquisition of pharmaceuticals from any source, including medications purchased at Federal Supply Schedule and the HRSA 340B pricing. Nor shall anything in the Pharmacy Agreement and all addenda thereto require the Provider to acquire drugs from the Plan Sponsor, the Plan or from any other source.

13. Point of Sale Processing.

Where the Part D Plan Sponsor's standard pharmacy agreement contains provisions related to drug utilization review and/or generic equivalent substitution and the Provider does not have the reasonable information technology capacity to comply with such, then the provisions shall not apply to the Provider. As specified in §423.132(c)(3) of the final rule, the notification of price differentials is waived for the Provider.

14. Submission of Claims.

The Provider may submit claims to the Plan by telecommunication through an electronic billing system or by calling a toll-free number for non-electronic claims; in the case of the latter, the Provider shall submit a confirmation paper claim.

15. Payment Rate.

Claims from the Provider shall be paid at rates that are reasonable and appropriate.

16. Information, Outreach, and Enrollment Materials.

All materials for information, outreach, or enrollment prepared for the Part D Plan shall be supplied by the Part D Plan to the Provider in paper and electronic format at no cost to the Provider.

17. Hours of Service.

The hours of service of the pharmacies or dispensaries of the Provider shall be established by the Provider. At the request of the Part D Plan, the Provider shall provide written notification of its hours of service to the Part D Plan.

18. Ethics language

An endorsement of a non-Federal entity, event, product, service, or enterprise may be neither stated nor implied by the IHS or IHS employees in their official capacities and titles. Such agency names and positions may not be used to suggest official endorsement or preferential treatment of any non-Federal entity under this agreement.

TRIBAL INDIAN HEALTH ADDENDUM TO MEDICARE PART D PLAN AGREEMENT

1. Purpose of Indian Health Addendum; Supersession.

The purpose of this Indian Health Addendum is to apply special terms and conditions to the agreement by and between _____(herein "Part D Plan Sponsor") and _____ (herein "Provider") for administration of Medicare Prescription Drug Benefit program at pharmacies and dispensaries of Provider authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Parts 403, 411, 417, 422 and 423 of Title 42, Code of Federal Regulations. To the extent that any provision of the Part D Plan Sponsor's agreement or any other addendum thereto is inconsistent with any provision of this Indian Health Addendum, the provisions of this Indian Health Addendum shall supercede all such other provisions.

2. Definitions.

For purposes of the Part D Plan Sponsor's agreement, any other addendum thereto, and this Indian Health Addendum, the following terms and definitions shall apply:

(a) The term "Part D Plan Sponsor" means a nongovernmental entity that is certified under 42 CFR Part 423 or 42 CFR Part 422 as meeting the requirements and standards that apply to entities that offer Medicare prescription drug plans.

(b) The terms "Part D Plan" means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in 42 CFR 423.272, 42 CFR 422.502 or 42 CFR 417.472 and that is offered by a PDP sponsor that has a contract with the Centers for Medicare and Medicaid Services that meets the contract requirements under subpart K of 42 CFR Part 423 or subpart K of 42 CFR Part 422.

(c) The term "Provider" means an Indian tribe, tribal organization or urban Indian organization which operates one or more pharmacies or dispensaries, and is identified by name in Section 1 of this Indian Health Addendum.

(d) The term "Centers for Medicare and Medicaid Services" means the agency of that name within the U.S. Department of Health and Human Services.

(e) The term "Indian Health Service" means the agency of that name within the U.S. Department of Health and Human Services established by Sec. 601 of the Indian Health Care Improvement Act, 25 USC §1661.

(f) The term "Indian tribe" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(g) The term "tribal organization" has the meaning given than term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(h) The term "urban Indian organization" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(i) The term "Indian" has the meaning given to that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(k) The term "dispensary" means a clinic where medicine is dispensed by a prescribing provider.

3. Description of Provider.

The Provider identified in Section 1 of this Indian Health Addendum is (check appropriate box):

/_/ An Indian tribe that operates a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 et seq.

/_/ A tribal organization authorized by one or more Indian tribes to operate a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 et seq.

/_/ An urban Indian organization that operates a health program, including one or more pharmacies or dispensaries, under a grant from the Indian Health Service issued pursuant to Title V of the Indian Health Care Improvement Act.

4. Deductibles.

The cost of pharmaceuticals provided at a pharmacy or dispensary of Provider or paid for by the Provider through a referral to a retail pharmacy shall count toward the deductible applicable to an IHS beneficiary enrolled in a Part D Plan.

5. Persons eligible for services of Provider.

(a) The parties agree that the persons eligible for services of the Provider shall be governed by the following authorities:

(1) The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Part 403 of Title 42, Code of Federal Regulations;
(2) Sec. 813(a) and Sec. 813(c) of the Indian Health Care Improvement Act, 25 USC §1680c (a) and (c);
(3) Part 136 of Title 42, Code of Federal Regulations; and
(4) The terms of the contract, compact or grant issued to Provider by the Indian Health Service for operation of a health program.

(b) No clause, term or condition of the Part D Plan Sponsor's agreement or any addendum thereto shall be construed to change, reduce, expand or alter the eligibility of persons for services of the Provider under the Part D Plan that is inconsistent with the authorities identified in subsection (a).

6. Applicability of other Federal laws.

The parties acknowledge that the following Federal laws and regulations apply to Provider as noted:

(a) A Provider who is an Indian tribe or a tribal organization:

(1) The Indian Self-Determination and Education Assistance Act, 25 USC §450 et seq.;
(2) The Indian Health Care Improvement Act, 25 USC §1601, et seq.;
(3) The Federal Tort Claims Act, 28 USC §2671-2680;
(4) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2; and
(5) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

(b) A Provider who is an urban Indian organization:

(1) The Indian Health Care Improvement Act, 25 USC §1601, et seq.;
(2) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2;
(3) The Federal Tort Claims Act, 28 USC §2671-2680 to the extent the urban Indian organization is a Federally Qualified Health Center;
(4) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

7. Non-taxable entity.

To the extent the Provider is a non-taxable entity, the Provider shall not be required by a Part D Plan Sponsor to collect or remit any Federal, State, or local tax.

8. Insurance and indemnification.

A Provider which is an Indian tribe or a tribal organization shall not be required to obtain or maintain general liability, professional liability or other insurance, as such Provider is covered by the Federal Tort Claims Act pursuant to Federal law (Pub.L. 101-512, Title III, §314, Nov. 5, 1990, 104 Stat. 1959, as amended by Pub. L. 103-138, Title III, §308, Nov. 11, 1993, 107 Stat. 1416 (codified at 25 USC §450f note); and regulations at 25 CFR Part 900, Subpt. M. To the extent a Provider that is an urban Indian organization is covered by the FTCA pursuant to section 224 of the Public Health Service Act (codified as 42 U.S.C. §233), and regulations at 42 C.F.R. Part 6, such Provider shall not be required to obtain or maintain general liability, professional liability or other insurance as such Provider is covered by the Federal Tort Claims Act pursuant to such designation. Nothing in the Part D Plan Sponsor's agreement or any addendum thereto shall be interpreted to authorize or obligate Provider or any employee of such Provider to operate outside of the scope of employment of such employee, and Provider shall not be required to indemnify the Part D Plan Sponsor.

9. Employee license.

Where a Federal employee is working within the scope of his or her employment and is assigned to a pharmacy or dispensary of Provider, such employee is not subject to regulation of qualifications by the State in which Provider is located. The parties agree that during the term of the Pharmacy Agreement, such Federal employees will be licensed in accordance with applicable Federal statutes and regulations. To the extent that any direct employee of Provider is exempt from State regulation, such employee shall be deemed qualified to perform services under the Part D Plan Sponsor's agreement and all addenda thereto, provided such employee is licensed to practice pharmacy in any State. This provision shall not be interpreted to alter the requirement that a pharmacy hold a license from the Drug Enforcement Agency.

10. Provider eligibility for payments.

To the extent that the Provider is exempt from State licensing requirements, the Provider shall not be required to hold a State license to receive any payments under the Part D Plan agreement and any addendum thereto.

11. Dispute Resolution.

In the event of any dispute arising under the Participating Pharmacy Agreement or any addendum thereto, the parties agree to meet and confer in good faith to resolve any such disputes. Any dispute hereunder that cannot be resolved by and between the parties in good faith shall be submitted to the dispute resolution procedure pursuant to the Participating Pharmacy Agreement.

12. Governing Law.

The Part D Plan Sponsor's agreement and all addenda thereto shall be governed and construed in accordance with Federal law of the United States. In the event of a conflict between such agreement and all addenda thereto and Federal law, Federal law shall prevail. Nothing in the Part D Plan Sponsor's agreement or any addendum thereto shall subject Provider to State law to any greater extent than State law is already applicable.

13. Pharmacy/Dispensary Participation.

The Part D Plan Sponsor's agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider. A pharmacy is required to use a National Council for Prescription Drug Programs (NCPDP) provider number for reimbursement. To the extent a dispensary does not have a NCPDP provider number, it is required to use an NCPDP Alternate Site Enumeration Program (ASEP) number for reimbursement.

14. Acquisition of Pharmaceuticals.

Nothing in the Part D Plan Sponsor's agreement and all addenda thereto shall affect the Provider's acquisition of pharmaceuticals from any source, including the Federal Supply Schedule and participation in the Drug Pricing Program of Section 340B of the Public Health

Service Act. Nor shall anything in such agreement and all addenda thereto require the Provider to acquire drugs from the Part D Plan Sponsor or from any other source.

15. Point of Sale Processing.

Where the Part D Plan Sponsor's standard pharmacy agreement contains provisions related to drug utilization review and/or generic equivalent substitution and the Provider does not have the reasonable information technology capacity to comply with such, then the provisions shall not apply to the Provider. As specified in §423.132(c)(3) of the final rule, the notification of price differentials is waived for the Provider

16. Claims.

The Provider may submit claims to the Part D Plan by telecommunication through an electronic billing system or by calling a toll-free number for non-electronic claims; in the case of the latter, Provider shall submit a confirmation paper claim.

17. Payment Rate.

Claims from the provider shall be paid at rates that are reasonable and appropriate.

18. Information, Outreach, and Enrollment Materials.

All materials for information, outreach, or enrollment prepared for the Part D Plan shall be supplied by the Part D Plan Sponsor to Provider in paper and electronic format at no cost to the Provider.

19. Hours of Service.

The hours of service of the pharmacies or dispensaries of Provider shall be established by Provider. At the request of the Part D Plan Sponsor, Provider shall provide written notification of its hours of service.