

Tribal Technical Advisory Group

To the Centers for Medicare & Medicaid Services

c/o National Indian Health Board 926 Pennsylvania Avenue, SE Washington, DC 20003 (202) 507-4070 (202) 507-4071 fax

January 11, 2011

Centers for Medicare and Medicaid Services
Attention: CMS-4144-P
P.O. Box 8013
Baltimore, MD 21244-8013

Via electronic submission to: <http://www.cms.hhs.gov/eRulemaking>

RE: Comments in response to proposed rule: Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Proposed Changes [CMS-4144-P]; 75 FED. REG. 71190, Nov. 22, 2010

These comments are submitted on behalf of the Tribal Technical Advisory Group (TTAG) chartered by the Centers for Medicare & Medicaid Services (CMS) to provide advice to the agency on Medicare, Medicaid, CHIP, and any other program funded (in whole or in part) by CMS with regard to policy issues that affect American Indians and Alaska Natives (AI/ANs) and the Indian health care delivery system.¹ A critical function of the TTAG is to advise CMS when consultation with Indian tribes should be undertaken and specific information-gathering regarding the impact of proposed agency actions is needed.

The Indian health care delivery system is comprised of the Indian Health Service (IHS), which provides direct services to AI/ANs; programs operated by Indian tribes and tribal organizations through Indian Self-Determination and Education Assistance Act agreements with the IHS; and urban Indian organizations supported by grants from IHS pursuant to Title V of the Indian Health Care Improvement Act. Collectively, these entities are referred to as "I/T/Us".

1. Proposed 42 C.F.R. §423.154: Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA-PD plans.

CMS Has Failed to Perform its Responsibility for Tribal Consultation. The proposed regulations would make extensive changes to the Medicare Prescription Drug Benefit program, and would, therefore, directly affect AI/AN Part D enrollees as well as pharmacies operated by I/T/Us. When the agency contemplates regulatory changes that would have a direct effect on Indian people and Indian health programs, Presidential executive orders and longstanding

¹ The Tribal Technical Advisory Group, established by charter in 2003, was incorporated into law in 2009 under the American Recovery and Reinvestment Act in 2009 (Pub. L. 111-5, Sec. 5005(e)(1)).

Departmental policies require advance consultation with Indian tribes on matters with tribal implications.² Unfortunately, no such consultation with tribal leaders was initiated by CMS, nor did the agency come to the TTAG for guidance on the aspects of these regulatory proposals that impact Indian health.

The agency's failure to undertake any form of advance interaction with Indian health representatives is particularly disappointing with regard to Part II.B.11 – Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities under PDPs and MA-PD Plans. This proposal would add a new §423.154 to implement the directive in Sec. 3310 of the Affordable Care Act to reduce waste of Part D drugs dispensed to enrollees who are residents of long-term care facilities. CMS proposes to require nearly all pharmacies that service LTC facilities to dispense brand-name drugs to Part D enrollees in increments of 7 days or less.

The ACA directed the Secretary to consult with relevant stakeholders in developing new dispensing techniques. CMS describes in some detail its affirmative efforts to consult with a myriad of LTC professionals and organizations; pharmacy networks; drug industry entities; and Part D plan sponsors over a course of several months in 2010 prior to issuing the notice of proposed rulemaking in the FEDERAL REGISTER on November 22, 2010.

Regrettably, however, the agency did not reach out to tribal LTC facilities or to I/T/U pharmacies that service them – or even to the CMS TTAG – while gathering views on implementation of 7-day-or-less dispensing prior to issuance of the proposed regulations. It is obvious that proposed §423.154 will impact Indian entities; this is evidenced by CMS's (belated) request in the NPRM for comments from I/T/U pharmacies that service LTC facilities on the question of whether they should be exempted from the 7-day dispensing limitations. *See* Notice at p. 71208.

While we appreciate that CMS acknowledges that Indian impact must be evaluated, solicitation of tribal input at this stage in regulations development is woefully late and wholly inadequate. Unless these entities routinely read the FEDERAL REGISTER and all CMS notices therein, tribal LTC entities and I/T/U pharmacies would not even be aware of the proposed 7-day limitation on LTC Part D drug dispensing. Seeking Indian input at this late date through this method does not fulfill the agency's responsibility for prior consultation, nor does it produce the depth of consideration and analysis that the consultation process is intended to supply. Furthermore, omitting tribal representatives from the extensive consultations conducted with other stakeholders deprived them of the opportunity to learn the concerns of those other entities and to benefit from participation in the dialogue.

As a result, CMS has no direct information on the impact the 7-day brand name drug dispensing limitation would have on tribal LTC facilities or on I/T/U pharmacies that service them. While the TTAG can and does offer below some areas about which inquiry should be made, the fact remains that local level impact has not been surveyed.

TTAG Recommendations. Under these circumstances, the TTAG believes that I/T/U pharmacies must be exempted from the 7-day-or-less dispensing limitation – just as intermediate

² *See* U.S. Department of Health and Human Services, *Tribal Consultation Policy*, Sec. 4 (Dec. 14, 2010).

care facilities for the mentally retarded and developmentally disabled and institutes for mental disease are proposed for exemption. CMS obviously consulted directly with the latter types of facilities and found good cause for proposing them for exemption from §432.154. *See* NPRM at p. 71208. Unless and until tribal LTC facilities and I/T/U pharmacies have a like opportunity to describe and evaluate impact, it would be irresponsible for CMS to impose the §432.154 limitations on those facilities. TTAG recommends that LTC facilities serviced by I/T/U pharmacies be uniformly exempted from the 7-day-or-less dispensing limitation.

Areas for Inquiry from I/T/U Pharmacies The TTAG identifies below some areas of inquiry that should be solicited from tribal LTC facilities and the I/T/U pharmacies that service them:

- What impact would proposed §432.154 have on costs incurred by the pharmacies? What adjustments in dispensing costs would be needed to assure that additional costs incurred for pharmacy staff, acquisition of containers (vials, bottles, units-of-use cards, etc.), product stocking and delivery, record-keeping and inventory are fully recovered?
- Is it reasonable to expect that Part D Plan sponsors will make the needed upward adjustments in dispensing fees to cover increased pharmacy costs? We are not persuaded that the revisions CMS proposes to the definition of "dispensing fees" will be sufficient to assure that Part D Plan sponsors will compensate pharmacies for the additional work that will be required to dispense brand-name drugs to LTC facilities in smaller quantities.
- Do I/T/U pharmacies have the capability to make more frequent deliveries of Part D brand name drugs to the LTC facilities they service without incurring additional cost? The answer to this question will be impacted by the distance between the pharmacy and the LTC facility and the frequency with which deliveries can reasonably and economically occur. We note that CMS is sensitive to the challenges faced by rural pharmacies in getting Part D drugs to beneficiaries in LTC facilities, and has proposed to phase-in the 7-day-or-less dispensing requirement for these entities over a two-year period. These same challenges must be examined for I/T/U pharmacies that service LTC facilities, as they, too, are often located in remote areas with significant distances between the pharmacy and the LTC facility.
- Would the 7-day-or-less dispensing limitation result in assessment of additional patient co-pays? If so, this would have significant economic impact on I/T/U pharmacies, most of which routinely absorb co-pays for their Indian patients.³ This impact must be evaluated.
- To what extent are tribal LTC facilities technologically equipped to adopt the proposed uniform dispensing techniques?

³ It is in recognition of this fact that CMS regulations exempt I/T/U network pharmacies from the requirement to disclose to a Part D enrollee the price difference between a brand-name drug and a therapeutically equivalent generic drug. 42 C.F.R. §423.132(c)(3).

- Do tribal LTC facilities have sufficient staff to perform the additional duties that would be required for ordering and receiving affected medications in more limited doses, or would they incur greater staff costs to perform these functions more frequently?

Excluded Drugs. CMS wisely proposes to exclude from the 7-day-or-less dispensing limitation drugs that are difficult to dispense in such increments. §423.154(b). Many of the enumerated drugs are ones that are dispensed in liquid form and may be administered to patients in varying or as-needed doses – such as eye drops, nasal sprays and ear drops. We do not find insulin products among the enumerated excluded drugs. For many diabetes patients, insulin is administered in varying doses depending upon the patient's individual needs on a given day. Therefore, we recommend that CMS consider excluding any brand-name insulin products administered by injection from the 7-day-or-less dispensing requirement.

The proposed regulations would exclude Part D generic drugs from the 7-day-or-less dispensation limitation. Nonetheless, at p. 71205 of the Notice, CMS signals its plan to undertake subsequent rulemaking regarding applying the 7-day-or-less dispensing limitation to Part D generic drugs, and encourages "the industry" to comment on how soon it can transition to such a requirement. Such inquiry should not be limited to the drug industry. The impact of applying the more limited dispensing quantity to generic drugs supplied by I/T/U pharmacies to LTC facilities must also be examined in the course of developing any future regulations on this topic.

Return and Reporting of Unused Drugs. Sec. 423.154(f) requires unused drugs to be returned to a LTC pharmacy and to be reported to the Part D plan sponsor. Please clarify whether the return and report directive applies only to a pharmacy that is part of a LTC facility or whether it also applies to a pharmacy that services a LTC facility. If this requirement is intended to include both LTC in-house pharmacies and pharmacies that service LTC facilities, then subsection (f) should be amended to exempt I/T/U pharmacies from this requirement. We make this request for the same reasons described above – that is, the impact of imposing such a return and report requirement on I/T/U pharmacies has not been evaluated and could well produce adverse effects.

**2. Proposed revisions to –
42 C.F.R. §423.100 (definition of "incurred costs"), and
42 CFR §423.464 (Treatment under out-of-pocket rule)**

ACA section 3314 amended Sec. 1860D-2(b)(4)(C) of the Social Security Act to treat as incurred costs of a Part D beneficiary costs that are borne or paid by the IHS, an Indian tribe or tribal organization, or an urban Indian organization. The effect of this amendment is to count toward a beneficiary's true out-of-pocket costs ("TrOOP") the value of prescription drugs supplied by an I/T/U pharmacy and to thereby enable a Part D beneficiary served by such a pharmacy to qualify for catastrophic coverage when his/her TrOOP requirement is reached.

To reflect this change in the law, CMS proposes to revise the above-referenced sections of the regulations. Upon review, the TTAG believes that the proposed regulatory revisions

contain technical errors that need to be corrected and also require revisions to achieve clarity. Our recommendations follow.

§423.100 – definition of "incurred costs". We set out below the text of CMS's proposed revision to this definition with our recommended changes to correct a citation error and improve clarity:

Incurred costs * * *

(2) * * *

(ii) Under a State Pharmaceutical Assistance Program (as defined in §423.464); by the Indian Health Service (~~as defined in section 4 of the Indian Health Care Improvement Act~~), an Indian tribe or tribal organization, or an urban Indian organization (all as defined in section 4 of the Indian Health Care Improvement Act and referred to as I/T/U pharmacy in ~~§423.464~~ §423.100) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service Act); or

We recommend re-locating the second parenthetical as the definitions of the Indian Health Service, Indian tribe, tribal organization and urban Indian organization are *all* found in Sec. 4 of the Indian Health Care Improvement Act. As written by CMS, the cross-reference to IHCIA Sec. 4 seems to apply only to the definition of the Indian Health Service. In addition, we note that the regulatory reference to "I/T/U pharmacy" is found in §423.100, not in §423.464. In fact, that latter section does not now use the term "I/T/U pharmacy", although the CMS proposed revision would introduce that term there through a cross-reference which also requires correction. Finally, the word "Act" was inadvertently omitted from the reference to the Public Health Service Act at the end of the clause.

§423.464 – Treatment under out-of-pocket rule. The CMS proposed revision to this section suffers from similar syntactical and citation infirmities. Suggested revisions follow:

(f) * * *

(2) * * *

(i) * * *

(B) Excluded expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage. Excluded expenditures do not include ~~payments made~~ costs borne or paid by the Indian Health Service (~~as defined in section 4 of the Indian Health Care Improvement Act~~), an Indian tribe or tribal organization, or an urban Indian organization (all as defined in section 4 of the Indian Health Care Improvement Act and referred to as I/T/U pharmacy in ~~§423.464~~ §423.100) or an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service Act).

We recommend replacing "payments made" with "*costs borne or paid*" to track the terminology used in ACA Sec. 3314; that language more accurately describes the nature of the economic involvement of an I/T/U pharmacy when dispensing a Part D drug to a beneficiary. Our suggested relocation of the cross-reference to IHCA Sec. 4 is intended to clarify that the definitions of all four terms – Indian Health Service, Indian tribe, tribal organization and urban Indian organization – are found there. We correct the citation to the regulatory provision where the term "I/T/U pharmacy" is defined (it is in §423.100), and add the word "Act" to the reference to the Public Health Service Act.

3. Other recommended revisions to 42 CFR §423.464 – coordination of benefits

ACA Sec. 2901(b) expressly designates health programs operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations as the payer of last resort for services provided to beneficiaries eligible for services from those entities, notwithstanding any Federal, State or local law to the contrary. The TTAG recommends that this statutory policy be reflected in the §423.464 regulation (regarding coordination of benefits) to assure that there is no question that Medicare Part D is a primary payer to I/T/U programs. Such an addition would be consistent with existing §423.464(b) which provides that Medicare Part D is primary payer to a State Pharmaceutical Assistance Program. Regulatory language for consideration follows:

§423.464 * * *

(b) Medicare as primary payer. The requirements of this subpart do not change or affect the primary or secondary payer status of a Part D plan and a SPAP or other prescription drug coverage. A Part D plan is always the primary payer relative to (i) a State Pharmaceutical Assistance Program and (ii) services provided by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act.

Current §423.464(f)(1)(v) lists the Indian Health Service⁴ under the definition of "other prescription drug coverage." In view of the ACA Sec. 2901(b) payer of last resort provision, is this reference to the Indian Health Service still appropriate? We ask because we believe CMS should make every effort to avoid any chance that an Indian Health Service-funded program would be expected to pay before Medicare Part D in a coordination of benefits activity.

4. Conclusion

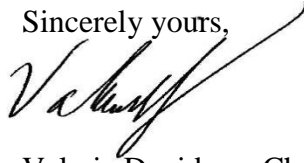
We respectfully urge CMS to accept the recommendations set out in these comments. They are needed to assure that the Secretary meets her obligation to carry out the Federal trust responsibility for Indian health,⁵ to protect I/T/U pharmacies and tribal LTC facilities, to reflect

⁴ The statutory reference in §423.464(f)(1)(v) is inaccurate. That reference should have read "Chapter 18 of title 25" of the United States Code. Chapter 18 of title 25 is the location of the Indian Health Care Improvement Act.

⁵ See 25 U.S.C. §1602.

relevant ACA provisions and to improve the clarity of the regulations. Thank you for your consideration.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Valerie Davidson', with a long, sweeping flourish extending to the right.

Valerie Davidson, Chair
CMS Tribal Technical Advisory Group

Cc: Members of the CMS Tribal Technical Advisory Group
Kitty Marx, Director, CMS Tribal Affairs Group