5 December 2014

TPP TRANSPARENCY & PROCEDURAL FAIRNESS CHAPTER JUSTIFICATION

Concerns that the Transpacific Partnership (TPP) Transparency and Procedural Fairness for Healthcare Technologies Annex will "undermine" critical U.S. health programs are unfounded. Existing U.S. law already require Federal agencies responsible for administering Federal healthcare programs to comply with standards at least as high as those in the proposed Annex. The TPP Annex will not alter these in any way.

The proposed TPP provisions are intended to offer the same due process in foreign markets protections that U.S. agencies accord in their proceedings. The Transparency and Procedural Fairness provisions list measures to provide greater transparency in the regulatory process governing reimbursement of drugs and medical devices, and ensure a fair process that offers notice-and-comment periods, sufficient time to implement regulations, and fair pricing practices.

The arguments against including Federal healthcare programs in the scope of the Transparency and Procedural Fairness' due process protections are based on three flawed concerns:

Concern 1: The TPP Transparency and Procedural Fairness Annex is problematic, in part, due to its requirements that Federal healthcare programs disclose procedural rules, methodologies, principles, and guidelines for pricing and reimbursement decisions.

Response 1: Federal healthcare programs are, in fact, required to disclose rules, methodologies, principles and guidelines. The TPP Annex would require other governments to bring their standards closer to those of the U.S., and implementing the Annex would require no new or amended laws or regulations in the U.S.

- Currently, U.S. Federal health care programs are subject to transparency obligations – resulting from statutory requirements or informal practice codified by decades of precedent – when promulgating rules, methodologies, principles, and guidelines, generally and regarding pricing and reimbursement specifically, that go far beyond the simple "disclosure" requirements of the TPF.[i,ii]

- For example, existing pricing methodologies for reimbursement of drugs and biologicals within Medicare and Medicaid were established through notice-and-comment rulemaking processes in line with these statutory requirements.[iii]

- Proposals for TPP's Transparency and Procedural Fairness Annex would require transparency obligations and disclosure requirements similar to those required by U.S. law, including notice-and comment-periods, guidelines on fair pricing practices, etc.

Concern 2: The Annex's transparency requirements, coupled with requirements that reimbursement is based on "market-derived prices", will reduce any government leverage to achieve the lowest pharmaceutical prices in Federal healthcare programs, and will expose the programs' price-setting processes to challenges under the trade agreement.

Response 2: Tying reimbursements to "market-derived prices" is current U.S. practice. It does not limit government leverage to achieve the lowest pharmaceutical prices, nor do transparency requirements. Moreover, the Investor-State Dispute Settlement (ISDS) mechanism would unlikely be applicable to cases concerning the Annex; ISDS covers expropriation, not procurement or reimbursement policy.

- Federal healthcare programs currently base reimbursement for drugs and biologicals on market-derived prices.[iv] Medicare makes determinations on which drugs should be bundled when provided in a hospital outpatient department based on market-derived pricing data.[v]
- The Medicaid rebate program is predicated on the market-derived "best price" that manufacturers offer any commercial (non-governmental) customer.[vi]
- No source of data other than market-derived prices could serve as, at least, the basis for setting reimbursements for products manufactured by private-sector entities to be used in a public-private marketplace.
- U.S. federal healthcare programs are unlikely to be at risk of challenges through ISDS under the Transparency and Procedural Fairness Annex because (1) these programs do not have the traditional "investors" covered by the ISDS provision, (2) ISDS only covers expropriation of property, not contract awards, and (3) there is precedent against claimants attempting to prove standing based on an argument around the expropriation of future potential profits by a Federal government.

Concern 3: The constraints of the annex's transparency requirements will limit Congress' future capacity to modify reimbursements.

As previously noted, the Annex requires no changes to U.S. law, and will not limit Congress' capacity to regulate in the future. Experience with other trade agreements is testament to this. Since the passage of the two free trade agreements that included similar provisions (Australia FTA, 2005; Korea FTA, 2011), there have been extensive healthcare policy changes in the U.S., none of which have been impacted by the FTAs. Neither trade agreement has resulted in any changes to U.S. healthcare programs, nor has either agreement prevented Congress from considering alternative payment and delivery of care models in Federal healthcare programs.[vii]

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[i] 5 U.S.C. § 551 *et seq*.
[ii] [ii] Agencies must issue a notice of proposed rulemaking (NPRM), allow for a public comment period, and issue a final rule that is not effective for at least 30 days from the date of issue (with limited exceptions), *See* 5 U.S.C. § 553 (d).
[iii] Methodologies related to average sales price in Medicare Part B, for example *See* 42 CFR 414.904; related to Medicaid Average Manufacturer Price, for example *See* 77 Fed. Reg. 5,318 (February 2, 2012); related to Medicaid Best Price, for example *See* 42 CFR § 447.505.
[iv] For example, Medicare reimbursement for separately paid drugs and biologicals administered in physician offices and in hospital outpatient departments is derived from market prices, *See* 42 C.F.R. § 414.904.
[v] For a detailed methodology *See* 70 Fed. Reg. 68,516, 68,363 (November 10, 2005).
[vi] *See* 42 U.S.C. § 1396r-8 (describing the Medicaid Drug Rebate Program).
[vii] For example, the Affordable Care Act (ACA) of 2010 altered the pricing methodology for drugs and biologicals under Medicaid, *See* ACA § 2501(a-f).