State Price Transparency Reporting (SPTR): Laws, Experience, Outlook, From Legal and Operational Perspectives

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State Price Transparency Reporting (SPTR): Laws, Experience, Outlook

- Introductions and Thanks
- State Price Transparency Reporting (SPTR) – Quick Summary
- Review of Active & Pending SPTR Laws – Legal and Operational Perspectives
- SPTR Experience – Some Lessons Learned
- SPTR Future Outlook
- Q & A

Introductions and Thanks

- Al Godley, VP Customer Solutions at ClassOne Insight
- Stephanie Trunk, Partner at Arent Fox
- Thanks for attending today
- Thanks for pharma & healthcare industry work
- Thanks to Informa for continued conferences
- Star of this show:

State Price Transparency Reporting

"SPTR"

(pronounced "sputter")

Intro to ClassOne Insight (1/2)

- ClassOne = Domain Expertise + Technology + Services
- ClassOne has domain expertise and practical experience in many pharma commercial operations functions
- ClassOne has extensive technology capability in data management and processing across five areas: aggregation, computation, analysis, reporting, delivery
- ClassOne provides solutions and services for managing and optimizing pharma commercial operations functions
- Over 100 pharma manufacturers use ClassOne solutions

Intro to ClassOne Insight (2/2)

ClassOne provides comprehensive SPTR solutions

- SPTR Processing – analysis of pricing data against all SPTR requirements, report generation, price increase planning
- SPTR Audit – verification and retroactive processing
- SPTR Library – state legislation, supporting documentation
- SPTR Compliance – compliance policies and processes, standalone or integrated with existing
- SPTR Consulting – on all aspects of the domain

Intro to Arent Fox and Stephanie Trunk

- Arent Fox is one of the leading law firms focused on the pharmaceutical industry
- Stephanie Trunk is a Partner, focused on regulatory, reimbursement, and compliance for pharma and medical device manufacturers
- Depth in drug pricing and government price reporting, HIPAA and privacy matters, counseling on Medicare Part D, developing corporate compliance programs, contract negotiations, and transactions

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SPTR Functional Overview (1/3)

- State Price Transparency Reporting (SPTR) includes diverse and evolving requirements from states for manufacturers to report on drug pricing
- Currently about 20 states with legislation (a few not yet active) and others in progress; expect to reach 30+
- Very little commonality across states
- Rules can be very complex – combinations of calculations, reports, and documentation are sometimes more complex than Government Pricing calculations & reporting
- Volume of processing and reporting can vary tremendously depending on nature of price increases

SPTR Functional Overview (2/3)

- Reporting requirements can include
  - Price increases, based on complex rules
  - Periodic, regardless of activity
  - Product launches, acquisitions, changes
  - State-specific target products
- Disparity across states in rules, formats, schedules
- Supporting documentation ("narratives") for price increase reports can be extensive and cross-functional (e.g. R&D, marketing)
- Fines assessed for not reporting (can be $thousands/day)

SPTR Functional Overview (3/3)

- Some aspects of SPTR management and operations can be similar to Government Pricing or Medicaid Rebate Processing, but many differences (especially due to breadth and variability)
- Management of SPTR usually spans several functions: contracts, pricing, finance, legal, compliance; plus others may be involved for documentation
- Various resources can be used to manage SPTR: legal advice, functional consulting, technology services (processing, analysis, reporting)

SPTR Legal Overview

- Failure to comply can result in significant fines for untimely reporting
- Some laws would permit fines for incomplete reports BUT have not witnessed levy for this YET
- Some states like Maine require registration even if nothing to report and can levy fines for failing to register
- Need to use diligence not to disclose confidential and propriety trade secrets or business information;
  some states permit disclosures limited to public domain and others allow marking trade secrets for non-disclosure, but no gurantee markings will be honored

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States With Active or Pending SPTR Laws

- California (CA)
- Colorado (CO)
- Connecticut (CT)
- Louisiana (LA)
- Maine (ME)
- Maryland (MD)
- Massachusetts (MA)
- Minnesota (MN)
- Nevada (NV)
- New Hampshire (NH)
- New Jersey (NJ)
- New Mexico (NM)
- New York (NY)
- North Dakota (ND)
- Oregon (OR)
- Texas (TX)
- Utah (UT)
- Vermont (VT)
- Virginia (VA)
- Washington (WA)
- West Virginia (WV)

Review of States: California (CA)

- Reporting: new products, price increases
- Legal perspective
  - PI: 16% in prior 2 CY
  - Extensive WAC data and narrative info requested, but can be limited to info in public domain; advance notice to purchasers
  - Significant fines and very active in demanding payment for untimely filing; success in settling but will pay something
- Operational perspective
  - One of the most active states in all aspects of SPTR activity
  - Has often been the most-triggered for price increases
  - Some manufacturers report more often than necessary following settlement of a fine or to avoid fines

Review of States: Colorado (CO)

- Reporting: new product, price increase (both to prescribers, not state)
- Legal perspective
  - Manufacturer must provide current pricing info to prescribers, so every new product introduction or price increase requires updating that documentation to remain current
  - Also requires names & prices of 3 generics in same therapeutic class
  - Only required if engaged in "prescription drug marketing"
  - Also has a prescription drug review board that has become active
- Operational perspective
  - Manufacturer needs current documentation of products and pricing reminders to provide pricing to prescribers
  - List of generics in same class usually managed outside SPTR ops

Review of States: Connecticut (CT)

- Reporting: new product (branded), price increase (if requested)
- Legal perspective
  - Reporting is based on a list of drugs developed annually by state; list is supposed to come by March 1 but is always late
  - State selects 10 products per year that have WAC > $60/treatment course and WAC (net of rebates to state in prior year) with increase 20% in prior CY or 50% in 3 CYs
- Operational perspective
  - New product report due date: inconsistency between legislation and guidelines (receipt of PDUFA date vs PDUFA date itself)
  - PI: very unlikely to land on the state's list

Review of States: Louisiana (LA)

- Reporting: periodic (quarterly), price increase
- Legal perspective
  - PI: 50% increase (timeframe not defined)
  - Not active in enforcement, no set penalties for late submission
- Operational perspective
  - Conservative approach is to consider multiple definitions of "50% increase" for triggering PI report (since last change, prior year)
  - Periodic report requests some obscure values (e.g. RxCUI #) and format is a little quirky (e.g. rejects some text characters)
  - PI report guide had some inconsistencies in examples

Review of States: Maine (ME)

- Reporting: new product, periodic (annual registration), price increase (1 required rule, 1 by request)
- Legal perspective
  - PI: (1) 20% in 1 year per pricing unit (1 pill, 1 ML, etc - like MDRP);
    (2) if requested by state, typically course of treatment > $2500
    and PI 15% in 12 months or 50% in 5 years
  - PI report requires extensive info on sales (unit and revenue), rebates, cost increase factors, etc; will be kept confidential
  - Fines up to $25,000 per occurrence but not very active – YET
  - Recently established an Affordability Board as well
- Operational perspective
  - Straightforward: medium threshold (not triggered often), report is detailed but accessible, legislation is well-documented
  - Requires annual registration renewal

Review of States: Maryland (MD)

- Reporting: new product (if requested)
- Legal perspective
  - Focus is on high-priced drugs
  - Required only if requested by the state
  - Affordability Board is starting to be more active with stakeholders at meetings
- Operational perspective
  - Straightforward report
  - No price threshold on new product report

Review of States: Massachusetts (MA)

- Reporting: pricing overall (if requested)
- Legal perspective
  - MA Health Policy Commission (HPC) may investigate pricing if MassHealth rejects pricing/rebates; "Referred Manufacturer"
  - Referred Manufacturer must submit extensive report that includes 5 years of pricing in US and int'l, history (trials, approval, efficacy), costs of mfg, sales/distribution, etc; and more
  - "Public Narrative" to summarize factors, suitable for public release
  - HPC/MassHealth may propose supplemental rebate
- Operational perspective
  - Manufacturer will be notified if need to report
  - In practice, rare and/or still ramping up reviews
  - Large amount of work if it happens!

Review of States: Minnesota (MN) (1/2022)

- Reporting: new product, price increase
- Legal perspective
  - PI: branded: 10% in 12 months or 16% in 24 months;
    generic: 50% in 12 months
  - Extensive reporting requirements: PI factors, WAC history, costs of manufacturing, marketing, distribution, sales, profit, PAP,…; information can be declared confidential to avoid public disclosure
  - New law – effective for increases after January 1, 2022
- Operational perspective
  - Not yet active, expect to be complex due to extensive requirements; other complex states required fixes/iterations
  - Expecting additional documentation from state about formats and submission (hopefully soon!)

Review of States: Nevada (NV)

- Reporting: periodic (limited), price increase (if requested)
- Legal perspective
  - Rules apply only to limited set of drugs (asthma and diabetes)
  - PI: requested if state determines manufacturer had PI greater than CPI-MedicalComponent in 1 year or 2x CPI-MC in 2 years
- Operational perspective
  - Manufacturer responsible for knowing if product is on NV Essential Diabetes and Asthma Drug List
  - Report formats are more complex than many other states

Review of States: New Hampshire (NH)

- Reporting: new product, price increase
- Legal perspective
  - PI: 20% per pricing unit in prior CY, minimal report info beyond previous and new WAC
  - Two separate new product requirements
  - State is still in process of operationalizing; working on guide and website/portal
- Operational perspective
  - Two separate requirements for new products, different state depts
  - PI reporting required info is minimal compared to others
  - Technical problems with registration and reporting

Review of States: New Jersey (NJ) (date tbd)

- Reporting: periodic (quarterly)
- Legal perspective
  - Legislation passed but not implemented by state (no funding)
  - Periodic reporting only (quarterly)
  - Only required if engaged in "prescription drug marketing," which also includes mail and email
- Operational perspective
  - Periodic reporting only (quarterly), not expected to be too complex
  - Unknown in practice because not implemented by state, no guidance published, very limited information available

Review of States: New Mexico (NM)

- Reporting: periodic (quarterly)
- Legal perspective
  - Mix of data required: AMP, lowest WAC paid by wholesaler in NM or default WAC if no NM wholesale shipments; price to PBMs, lowest direct price (non-wholesale), prompt-pay discounts paid
  - Pre-dates most current SPTR laws, usually handled by GP team
- Operational perspective
  - Requires obtaining data from other internal sources (e.g. GP calculations/reports)
  - Some companies are moving this responsibility to be part of SPTR function; feasible if SPTR team can easily access GP data

Review of States: New York (NY)

- Reporting: price increase (if requested)
- Legal perspective
  - Price increase reporting if requested
  - May be requested if state can't reach Medicaid rebate agreement for a product and state expenditure on it is projected to exceed annual growth limit
- Operational perspective
  - Manufacturer will be notified if need to report
  - In practice, very rare for state to request manufacturer report

Review of States: North Dakota (ND) (10/2021)

- Reporting: new product, periodic (quarterly), price increase
- Legal perspective
  - PI: 10% in 12 months or 40% in prior 5 CY
  - Report requires rebates to PBMs, R&D, other factors in narrative; but may limit to info in public domain because reports will be public
- Operational perspective
  - Multiple triggers (one-year and five-year) and low thresholds result in potential for frequent reporting
  - Also new product and periodic reporting; overall potential to be one of the busiest states

Review of States: Oregon (OR)

- Reporting: new product, price increase
- Legal perspective
  - PI: (1) 10% in prior CY;
    (2) branded: 10% or $10K in 12 months;
    generic: 25% and $300 in 12 months
  - Extensive report content: sales, profit, costs (R&D, mfg, mktg, sales), international prices, generics; can request confidentiality
  - Process to mark information as a "trade secret" – must include specific reasons based on public record act exemption
  - Recently created an Affordability Board that is becoming active
- Operational perspective
  - Long-lead time on new product report (60 days)
  - Two separate PI reporting rules, different criteria and due dates
  - Reports have to be manually entered in state site
  - Variable fee based on number of reports submitted

Review of States: Texas (TX)

- Reporting: periodic (annual), price increase
- Legal perspective
  - PI: 15% in prior CY or 40% in prior 3 CY
  - Report includes R&D and other factors; also new drugs approved and drugs that went off-patent; can limit to public-domain info
  - Oddly quiet from an enforcement perspective – so far!
- Operational perspective
  - Periodic (annual) and price increases
  - Recently changed ownership in state; likely will be change to report content and format, and submission process

Review of States: Utah (UT) (1/2022)

- Reporting: price increase
- Legal perspective
  - PI: 10% in prior CY or 16% in 2 CY
  - Report includes R&D and other factors; also new drugs approved and drugs that went off-patent; can limit to public-domain info
  - Not yet effective; starts January 1, 2022
- Operational perspective
  - Currently limited guide information available
  - Specifications for reports or submission process not yet available; hopefully soon!

Review of States: Vermont (VT)

- Reporting: new product, price increase (if requested); also periodic (but not typical SPTR)
- Legal perspective
  - PI: Only if requested by state based on state expenditures and criteria: state will identify max of 10 drugs with increase of 15% in prior CY or 50% in 5 CYs
  - Supposed to publish lists June 1st of each year
- Operational perspective
  - Very unlikely for manufacturer to receive PI-based request because many drugs meet criteria but max of 10 are selected for reporting
  - Only state that requires submissions in PDF files
  - Periodic AWP-based reports (competitive products) related but usually managed outside SPTR ops

Review of States: Virginia (VA) (1/2022)

- Reporting: new product, periodic, price increase
- Legal perspective
  - PI: branded: 15% in prior CY;
    generic: 200% in 12 months
  - Report includes R&D and other factors; also new drugs approved and drugs that went off-patent; can limit to public-domain info
  - Not yet effective; starts January 1, 2022
- Operational perspective
  - No specifications or guidance yet on report format or submission
  - Hopefully they won't wait until December to publish info!

Review of States: Washington (WA)

- Reporting: new product, price increase
- Legal perspective
  - PI: 20% in prior CY or 50% in 3 CY
  - Report includes R&D, sales, rebates costs of trials, mktg, sales; and other factors
  - New drug threshold much higher than other states: $10,000 per 30 day supply or course of therapy
- Operational perspective
  - Long lead-time on PI reports (60 days)
  - Sometimes new products reported alongside price increases, separate from new product requirements
  - History: issues at intro: unclear specs and guidance (several iterations), complex retroactive reqs; all clear now, cautionary tale!

Review of States: West Virginia (WV)

- Reporting: periodic, price increase
- Legal perspective
  - PI: 15% in prior CY, 40% in 3 CY
  - Report includes R&D and other factors; also sales of drugs that went off-patent in past three years; may limit to public domain info
  - Expect this state to be active in enforcement!
- Operational perspective
  - Five distinct report templates:
    Annual WAC, WAC increase, mfg info, R&D cost, patent loss
  - Periodic report has a $-based filter-criteria (>$100/30-day supply); only state with a periodic criteria like this

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Observations From SPTR Work: Don't underestimate the complexity!

- Understanding state rules and requirements with respect to specific products
- Data quality needed for SPTR processing, including technical and functional accuracy
- Rule calculations require precision, not approximation
- Narratives can be cross-functional and involve legal issues
- Large variation in potential reporting requirements across states resulting from one action (e.g. price increase)
- Human elements of report submission are inconsistent
- State rules, guidance, oversight can all change!

Observations From SPTR Work: Some examples of states' complexity

- Functional issues such as inconsistent treatment of generics, authorized generics, biosimilars; lack of clarity about doses and courses of treatment, etc.
- Conflicting information and sometimes bad math: one calculation example didn't match rule definition; another had an error in calculation example
- Using formats that are unconventional in other government reporting or other technical situations
- Rejecting standard data formats despite requesting data from standard sources
- Rejecting files simply because external filenames don't conform, even if internal data fully conforms

Observations From SPTR Work: Some examples of states' complexity (con't)

- Inaccurate references to other sources (eg other laws)
- Conflicting information within one state's definitions
- Unannounced changes in state laws, sometimes via "guidelines" rather than full legislative process
- Subtle changes in definitions or interpretations that require deep expertise to identify and understand
- Unannounced changes to implementation of state systems, resulting in inconsistent handling within a period
- Requirements administered by different divisions of a state government, with different oversight or interpretations
- Different articulation and format of the same information across different states

Observations From SPTR Work: A more structured and rigorous approach

Many manufacturers are taking a more structured and rigorous approach to SPTR

- More attention to legal issues
- More integration with compliance functions
- More coordination with pricing functions/committees
- More robust data management and processing
- Auditing previous years' SPTR activity / delinquency
- Accessing external resources for legal advice, functional consulting, operational processing, technical support, report submission

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Future Outlook – Legal Perspectives

- New types of SPTR laws creating Affordability Boards – can ask for reports but can set a state "governor" on reimbursement for given drugs
- State legislature season largely over but many organizations are "shopping" model SPTR laws in states
- Expect more laws in 2022 absent federal action
- Expect more states to try to levy penalties and fines

- Be compliant but be careful – try to reveal only what is in SEC filings/public domain

Future Outlook – Operational Perspectives

- There are still many states that might jump into SPTR, so scope and complexity will continue to increase
  - Some recent laws and legislation appear to be modeled on existing laws in other states, but always many differences
  - Ongoing changes, additions, updates to existing laws
- Manufacturers evolving organizations, roles, processes to support SPTR; also budget considerations
- Drug Advisory and Affordability Boards can add additional complexity to the SPTR domain
- Federal legislation? Seems unlikely, but if so it will probably be additive, not superseding state laws
- Mandates for simple/effective Patient Assistance Progs

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