Recap Report:
National Leadership Summit on 340B

June 10, 2014
Washington, D.C.

Sponsored By:
AIRx 340B
Alliance for Integrity and Reform
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Overview

More than 80 leaders from a broad spectrum of stakeholders including community health centers, patient and specialty organizations, industry and academia convened in Washington, D.C. on June 10, 2014, for the first-ever National Leadership Summit on 340B. Organized and facilitated by the Alliance for Integrity and Reform of 340B (AIR 340B) and moderated by Cliff Goodman, Senior Vice President at the Lewin Group, the Summit fostered an open dialogue on key issues facing the 340B Drug Discount Program (340B), focusing on challenges within the program and how they can be addressed, as well as the importance of the program to health care facilities serving medically at-risk, underserved patients. While general agreement on certain aspects was reached, the purpose of the Summit was not to force consensus but rather to engage in a transparent discussion from multiple perspectives. The Summit did not put any particular findings or resolutions to a vote, and the participation of a Delegate did not necessarily imply his or her agreement with any or all of the findings reported.

Summit Highlights

Throughout the day, Delegates engaged in a thoughtful discussion and, while acknowledging the need for further collaborative deliberations, Delegates broadly recognized two divergent realities of the 340B program:

- The 340B program is essential to the ability of many Health Resources and Services Administration (HRSA)-grantees to serve medically at-risk communities. These covered entities have unique patient-centric governance and accountability mechanisms in place that enable these facilities to adhere to the mission of the program.
- 340B Disproportionate Share Hospital (DSH) expansion has created unintended, negative consequences for some patients, physicians and payers that may require the need for better oversight and perhaps both regulatory and legislative reform.

In order to ensure that the program thrives and remains viable for institutions treating underserved patient populations, Delegates acknowledged several main themes, including:

- The need to ensure that 340B covered entities are utilizing the program to support the needs of their medically underserved patients;
- Reevaluating hospital eligibility criteria to ensure 340B discounts go to the facilities that are taking care of medically underserved patients and providing appropriate levels of charity care; and
- Transparent accounting for all cost-savings derived from the 340B program.

At its conclusion, Delegates voiced appreciation for hearing new perspectives and information they had not heard previously from other 340B stakeholders, indicating that the overarching goal of the Summit - to present differing viewpoints on this challenging issue and find areas of general recognition or agreement - was met. The Summit featured two panels followed by robust discussion and a keynote presentation.

First Panel: What New Evidence Shows Us

- Jeffrey Ward, MD, Chair, Payment Reform Workgroup, Immediate Past Chair, Clinical Practice Committee, American Society of Clinical Oncology; Swedish Cancer Institute Edmonds
- Rena Conti, PhD, Assistant Professor of Health Policy and Economics, The University of Chicago
- Aaron Vandervelde, Director, Berkeley Research Group
- Murray Aitken, Executive Director, IMS Institute for Healthcare Informatics
The morning panel, “What New Evidence Shows Us,” provided Delegates with an opportunity to hear directly from researchers regarding analyses detailing the rapid growth of the 340B program, specifically among DSH hospitals offering cancer-care services, and how this expansion impacts the health care system. Delegates engaged in a constructive dialogue with the panelists and addressed specific data points raised in the presentations.

**Dr. Jeffrey Ward**, immediate past chair of the American Society of Clinical Oncology’s (ASCO) Clinical Practice Committee and current chair of their Payment Reform Workgroup presented ASCO’s recently released “Policy Statement on the 340B Drug Pricing Program,” which was developed due to “concerns about the 340B program” that “demanded attention.”

- The report recommended ways to improve the 340B program, including requiring an accounting of annual 340B savings and the percent reinvested into care; replacing the current DSH eligibility metric with a formula that considers the percent of underserved patients treated in the outpatient setting; defining and clarifying the term “patient”; providing adequate funding for HRSA’s auditing and program management functions; and examining how expansion of the program impacts community oncology practices.

- Dr. Ward also provided his personal account of merging his practice with a 340B hospital in Washington and summarized that “340B is essential in some circumstances for institutions to provide care to uninsured, indigent patients, but there has been expansion beyond the original intent of the program, which needs to be addressed in order to protect integrity and sustainability.”

**Dr. Rena Conti**, Assistant Professor of Health Economics and Policy at the University of Chicago, presented research on the growth of the 340B program and the increase in contract pharmacy arrangements noting that, “there has been a lot of worry about the expansion of the program.”

- Dr. Conti presented research suggesting that 340B profitability has led to hospitals “making acquisitions in more affluent areas,” whereas the manner in which HRSA-grantees care for underserved populations is more congruent with the intent of the program.

- She also reported research using Walgreen’s contract pharmacy prescription data, which found that generic medications were 50% more likely to be distributed in the general population than in the 340B population overall, suggesting that financial incentives arising from 340B affect prescribing patterns.

**Aaron Vandervelde**, Director at the Berkeley Research Group, presented two studies, the first documenting that a large number of 340B hospitals had acquired community oncology practices in wealthier areas, resulting in increased revenue for those hospitals through 340B savings.

- Mr. Vandervelde’s research echoed Dr. Conti’s analysis of this trend; however, his research found no correlation between these 340B savings and higher charity care spending. This finding was echoed in an AIR 340B report with analysis conducted by Avalere Health, which found that charity care represents less than 1% of total patient costs at approximately one-quarter of 340B hospitals.

- Mr. Vandervelde also reviewed a more recent study that showed Medicare and Medicare beneficiaries incurred additional costs of $196.55 million from 2009-2012 for chemotherapy claims, attributable to 86 340B hospitals’ acquisitions of physician-based oncology practices, a result of both increased utilization and higher reimbursement rates in hospital outpatient departments.

**Murray Aitken**, Executive Director at the IMS Institute for Health Informatics, presented research on increased costs borne by oncology patients and payers when care is administered in the hospital outpatient setting as opposed to the physician-based practice, which can lead to decreased adherence rates.
Specifically, Mr. Aitken reported that the covered cost per dose increased by 189% in the hospital outpatient setting when compared to the oncologist’s office and the average increased cost to the patient is $134 per dose received, based on 2012 data.

Post-Panel Discussion

- **Dan Hawkins**, National Association of Community Health Centers, noted that while consolidation may be occurring in hospital institutions, he believes that other elements beyond 340B may be contributing factors.
- **Jim Donnelly**, Hudson Headwaters, commented in regard to Dr. Conti’s findings related to disproportionately high brand dispensing rates with contract pharmacies, stating that contract pharmacy processing fees may make it more financially feasible for lower priced generics to be dispensed outside of 340B, and that this is not an indication that 340B providers are overprescribing branded drugs. **Chris Hatwig** from Apexus echoed that point.
- **Mr. Donnelly** also noted that the number of contract pharmacy arrangements referenced by Dr. Conti was inflated due to a misinterpretation of the Office of Pharmacy Affairs’ (OPA) database structure, citing the difference in the number of contract pharmacies and contract pharmacy arrangements.
- **Dr. Ward** commented that reimbursement instability was a major factor in his decision to merge with a 340B hospital and raised the possibility that community oncology clinics aren’t always available in less affluent areas.
- **Sean Donohue**, Eli Lilly, questioned previous Congressional Budget Office’s scoring of estimated federal savings based on 340B expansion since Mr. Vandervelde’s consolidation research showed an increase in Medicare spending; discussions noted that the Affordable Care Act (ACA) deliberations did not anticipate the amount of consolidation seen today.
- **Donald Moran**, Moran Company, suggested that 340B has become a statutory mechanism for price arbitrage, with little evidence that this mechanism benefits patients.
- **Joe Pugliese**, Hemophilia Alliance, mentioned that comprehensive hemophilia treatment centers serve both insured and uninsured patients, and that 340B is the critical source of funding. Pugliese also referenced that factor concentrate manufacturers have issued statements in support of comprehensive hemophilia treatment centers and the use of the 340B program as a source of funding for comprehensive hemophilia care.
- **Everett Crosland** from the Plasma Protein Therapeutics Association suggested that there needs to be a clear distinction between HRSA-grantees and DSH hospitals when addressing 340B; this developed into a major theme throughout the day. Crosland questioned whether there were other services outside of traditional charity care, such as social work, that could be identified as patient-support services.

Moderator **Cliff Goodman** summarized the major takeaways from the panel, including consolidation and the extent to which 340B is the prime driver given the presence of other reimbursement/market factors, financial incentives arising from 340B, whether any such incentives are consistent with the program’s mission, and whether the program has any adverse impacts on patient access. The session concluded with a discussion on whether 340B provides an incentive for prescribing brand medications over generics; however, some Delegates questioned whether drug prices and discounts influence doctors’ prescribing patterns.

**Keynote: Commander Krista Pedley, Director of the Office of Pharmacy Affairs (OPA) at HRSA**

Stating in her opening remarks that she was “grateful for this rare opportunity to speak to such a diverse group of stakeholders,” Commander Pedley reviewed some of the oversight activities underway within HRSA that have
expanded due to the Omnibus bill that increased the OPA budget by $6 million for FY 2014. In particular, Commander Pedley cited a new 340B program integrity effort designed to address compliance.

- Specifically, the funding will assist: “balanced efforts” to conduct covered entity and manufacturer audits; annual recertification programs; staff increases within OPA’s data, purchasing and pricing departments; and a new, comprehensive data system to ensure program integrity.
- Commander Pedley mentioned that OPA is able to conduct more audits in the field and identify entities that display “risk-based criteria,” which can more easily facilitate appropriate audits. She suggested that the increase in audits and improved data-tracking abilities have led to a sentinel effect, whereby covered entities are augmenting their compliance efforts.
- She also touched on OPA’s efforts in tracking and monitoring contract pharmacy arrangements to ensure covered entities are certifying their contract pharmacies, and taking appropriate steps to guard against diversion and duplicate discounts.
- Commander Pedley addressed the pending HRSA mega-rule in light of the recent federal court decision vacating HRSA’s 2013 final rule on orphan drug exclusion for certain 340B covered entities. She stated that HRSA strongly supports the intent of the program and that the Agency is reviewing the decision very carefully. She noted that “HRSA needs clear policies so that both manufacturers and covered entities can comply,” and she expressed a willingness to work with stakeholders and Congress to ensure that the 340B program is operating in the most efficient and transparent manner. Without addressing specifics on the mega-rule, Commander Pedley stated that “HRSA needs to be in a place to provide necessary oversight of the program.”

**Second Panel: Implications for the Health Care Delivery System**

- **Jim Donnelly**, Vice President of 340B Pharmacy Services, Hudson Headwaters Health Network
- **Michael Diaz**, MD, Board of Directors, Community Oncology Alliance; Florida Cancer Specialists
- **Crawford Clay**, Patient Support Advocate, Colon Cancer Alliance

The afternoon panelists shared their real-world perspectives on the 340B program based on their unique experiences.

**Jim Donnelly**, Vice President of 340B Pharmacy Services at Hudson Headwaters Health Network, a community health center in upstate New York, outlined the rigorous compliance efforts required of his facility by virtue of its eligibility as a Federally Qualified Health Center (FQHC), which also act to ensure that it meets the 340B program’s intent and provides services to underserved patients.

- Donnelly noted that many times, “community health centers may be the only site of care patients can access,” and that 340B is one of many supporting mechanisms these facilities need to operate.
- He talked about his facility’s federal FQHC grant requirement to treat all patients regardless of coverage, and their reliance on contract pharmacies to dispense medications.
- Donnelly noted that the federal FQHC grant requires that patients represent 51% of the center’s board of directors, a governance mechanism praised by several Delegates.
- He concluded by highlighting that the 340B program is a crucial element to community health centers’ stability and that these facilities undertake rigorous compliance and transparency initiatives to ensure program integrity.

**Dr. Michael Diaz**, a member of the Board of Directors of the Community Oncology Alliance, provided several examples experienced by his colleagues in Florida and across the country.
Dr. Diaz presented patient and provider stories about the increased pressure oncologists feel to merge with 340B hospitals and the impact on patient access and costs.

He posited that doctors “don’t have much of a choice” when faced with the decision to merge with hospitals, and that his colleagues who have chosen to keep their practices have reported losing insured patient referrals to 340B hospitals, but are still receiving uninsured patient referrals.

Dr. Diaz observed that such a scenario is contrary to the intent of the program, as 340B covered entities should be treating uninsured patients.

He highlighted instances of interruptions in patient care that seem driven by hospitals’ incentives to maximize 340B revenues; such instances include requiring patients to receive their medications at separate locations, often times with separate cost-sharing requirements.

Crawford Clay, a Patient Support Advocate at the Colon Cancer Alliance, shared his personal experience as a colon cancer patient and as a case manager helping patients afford transportation to their sites of care.

Clay recalled one patient who reported traveling four hours one way to receive care in the hospital, leading the patient to question whether the necessary and life-saving treatment was ultimately worth the effort.

He relayed the significant expense that accompanies cancer treatment for many of the patients he helps, who report having to travel long distances to the hospital, and increased cost-sharing, which may cause a patient to second-guess his or her treatment.

Clay also shared that he has helped many uninsured patients find access to 340B facilities at which they received treatment, referring to those cases as “clear 340B success stories.” Clay recognized the need for 340B to serve at-risk patients and hoped the Summit could make headway in reducing some of the unintended access problems patients have reported to his organization.

Post-Panel Discussion

Delegates deliberated on 340B hospital consolidation and whether a DSH-based metric is an appropriate eligibility criterion for hospital participation in the 340B program, as some of these hospitals reportedly are not passing savings along to underserved patients—in contrast to HRSA-grantees that are required to use program revenue for purposes of their grant. As such, DSH status may not be a strong indicator of whether a hospital is treating underserved patients. Delegates raised the possibility that, in 2014, more than 20 years after the program’s establishment, there may now be more suitable criteria to identify hospitals that treat large populations of underserved patients.

Several Delegates considered whether 340B hospitals should have compliance requirements similar to those of the HRSA-grantees, which could help to alleviate concerns that underserved patients are not benefitting from the program; however, other Delegates cautioned that any replacement criteria or related metrics should be carefully evaluated.

Delegates commented that the research presented at the Summit analyzed 340B and the impact on cancer treatment hospitals, and that other, public hospitals serve patients whose demographics closely mirror those served by community health centers. Delegates noted that, while this discussion is important, cancer hospitals only represent a specific segment of the 340B program and that a much larger discussion is needed when considering potential reforms.
Concluding Analysis

Recurrent themes and additional topics to explore include:

- Refocusing the 340B program on facilities that treat a large proportion of medically vulnerable and underserved outpatients. More specifically, potentially tying entity eligibility to treatment of underserved patients.
- Delegates engaged in a robust discussion regarding the fact that the uninsured patient population is not the only patient population in need of assistance with outpatient medications. Many patients are underinsured or underserved, especially those with minimal coverage, who have selected coverage that imposes relatively high prescription cost-sharing requirements, or who are otherwise at risk for diminished access to needed health services. Delegates suggested all such needy patients should be considered when evaluating a provider’s eligibility for the program.

The day’s deliberations generally recognized a clear distinction between HRSA-grantees and other providers that utilize 340B in accordance with the program’s intent, and those DSH hospitals that have generated substantial revenue through the program without any requirement to pass savings on to needy patients. Another related consequence is diminished patient access to affordable care, as community clinics are consolidated with hospitals competing for 340B revenue. Delegates affirmed that specific changes should be considered in order to bolster transparency, compliance and oversight of this important program.

Research

For more information on the research presented please contact AIR 340B at info@340Brefom.org or refer to the AIR 340B website, www.340Brefom.org.
The National Leadership Summit on 340B
June 10, 2014
The Newseum - Washington, DC

AGENDA

9:00 AM
REGISTRATION & BREAKFAST

9:30 AM
WELCOME & OPENING REMARKS
Moderator:
Cliff Goodman, Senior Vice President and Director, Center for Comparative
Effectiveness Research, Lewin Group

10:00 AM
WHAT NEW EVIDENCE SHOWS US
Discussion Leaders:
Jeffery Ward, MD, Chair, Payment Reform Workgroup, Immediate Past Chair,
Clinical Practice Committee, American Society of Clinical Oncology; Swedish
Cancer Institute Edmonds
Rena Conti, PhD, Assistant Professor of Health Policy and Economics, The
University of Chicago
Aaron Vandervelde, Director, Berkeley Research Group
Murray Aitken, Executive Director, IMS Institute for Healthcare Informatics

12:00 PM
LUNCHEON KEYNOTE:
Speaker:
Krista M. Pedley, PharmD, MS, CDR, USPHS, Director, Office of Pharmacy
Affairs, Health Resources and Services Administration

1:00 PM
IMPLICATIONS FOR THE HEALTH CARE DELIVERY SYSTEM
Discussion Leaders:
Jim Donnelly, Vice President of 340B Pharmacy Services, Hudson Headwaters
Health Network
Michael Diaz, MD, Board of Directors, Community Oncology Alliance; Florida
Cancer Specialists
Crawford Clay, Patient Support Advocate, Colon Cancer Alliance

2:30 PM
AREAS OF CONSENSUS & ACTION

3:30 PM
CONCLUSION
PARTICIPANTS OF THE 2014 NATIONAL LEADERSHIP SUMMIT ON 340B

Delegates

Steven Benz, Assistant General Counsel, Eli Lilly & Co.
Maya Bermingham, Vice President and Senior Counsel, PhRMA
Alison Bonebrake, Director, Federal Government Affairs, Sanofi
Barry Brooks, MD, Chairman, Pharmacy & Therapeutics Committee, The US Oncology Network
Everett Crosland, Director, Plasma Protein Therapeutics Association
Sean Donohue, Senior Director, Federal Health Affairs, Eli Lilly & Co.
Matthew Farber, Director, Provider Economics and Public Policy, Association of Community Cancer Centers
John Haddow, Partner, Upstream Consulting
Chris Hatwig, President, Apexus 340B Prime Vendor Program
Dan Hawkins, Senior Vice President, Public Policy & Research, National Association of Community Health Centers
Michelle Herzog, Deputy Director, Office of Pharmacy Affairs, Health Resources and Services Administration, U.S. Department of Health and Human Services
Patrick Kelly, Executive Vice President, Healthcare Distribution Management Association
Perry Knight, Senior Counsel, Johnson and Johnson/ Janssen
Holli Kubicki, Policy Analyst, Office of Pharmacy Affairs, Health Resources and Services Administration, U.S. Department of Health and Human Services
Elizabeth Lee, Policy Advisor, Health Resources and Services Administration
Andrea Maresca, Director of Federal Policy and Strategy, National Association of Medicaid Directors
Arielle Mir, Assistant Director, Medicare Payment Advisory Commission
Donald Moran, President, The Moran Company
Shelley Fuld Nasso, Chief Executive Officer, National Coalition for Cancer Survivorship
Ted Okon, Executive Director, Community Oncology Alliance
Thair Philips, President, RetireSafe
Joe Pugliese, President, The Hemophilia Alliance
Katheryne Richardson, Senior Director, 340B Program and Policy Analysis, Apexus, 340B Prime Vendor Program
Carl Schmid, Deputy Executive Director, The AIDS Institute
Andy Swire, Executive Director, Amgen, Inc.
Susan Thornton, Chief Executive Officer, Cutaneous Lymphoma Foundation
Laurel Todd, Managing Director, Reimbursement and Health Policy, BIO
Joel White, President, Horizon Government Affairs

Speakers & Panelists

Murray Aitken, Executive Director, IMS Institute for Healthcare Informatics
Crawford Clay, Patient Support Advocate, Colon Cancer Alliance
Rena Conti, PhD, Assistant Professor of Health Policy and Economics, The University of Chicago
Michael Diaz, MD, Board of Directors, Community Oncology Alliance; Florida Cancer Specialists
Jim Donnelly, Vice President of 340B Pharmacy Services, Hudson Headwaters Health Network
Cliff Goodman, Senior Vice President and Director, Center for Comparative Effectiveness Research, The Lewin Group
Krista M. Pedley, PharmD, MS, CDR, USPHS, Director, Office of Pharmacy Affairs, Health Resources and Services Administration, U.S. Department of Health and Human Services
Aaron Vandervelde, Director, Berkeley Research Group
Jeffery Ward, MD, Chair, Payment Reform Workgroup, Immediate Past Chair, Clinical Practice Committee, American Society of Clinical Oncology; Swedish Cancer Institute Edmonds
Attendees

Derek Asay, Senior Director, Government Strategy, Eli Lilly & Co.
Kristin Bass, Senior Vice President, Pharmaceutical Care Management Association
Jenni Brewer, Deputy Vice President, PhrMA
Kim Cantor, Vice President, Advocacy and Government Relations, Lupus Foundation of America
David Chen, Senior Director, Section of Pharmacy Practice Managers, The American Society of Health-System Pharmacists
Tracy Cooley, Senior Director, Communications, BIO
Andrew Cosgrove, Vice President, Pharmaceutical Care Management Association
John Coster, Principal, Coster Rx Policy Solutions, LLC
Erin Lewis Darling, Executive Director and Counsel, Merck
Rebecca Davidson, Senior Manager, PhRMA
Colleen DiClaudio, Vice President, 340Basics
Heather Dixson, Director, Government Price Reporting, Eli Lilly & Co.
Susan Friedman, Deputy Director of Government Relations, American Osteopathic Association
Shelagh Foster, Director, Government Relations, American Society of Clinical Oncology
Jaqueline Ferguson, Eli Lilly & Co.
Ally Funk, Director of Communications, PhRMA
Erin Hertzog, Director, Reimbursement and Health Policy, BIO
Sarah Holko, Associate, Berkeley Research Group
Yana Juroviski, Director, Public Affairs, Blue Ribbon Advocacy Alliance
Kevin Kirby, Partner, The Moran Company
Susan Kornetsky, Director, Federal Reimbursement, Sanofi
Mary Kruczynski, Director of Policy Analysis, Community Oncology Alliance
Brittany La Couture, Health Care Policy Analyst, American Action Forum
Virginia Ladd, President, American Autoimmune Related Diseases Association
Sean McGraw, Senior Director, Alliance Development, PhRMA
Jed Perry, Director, Federal Affairs and Operations, Baxter
Britten Pund, Senior Manager, Health Care Access, National Alliance of State and Territorial AIDS Directors
George Purdue, Chief Administrative Officer, Hudson Headwaters
Rachel Sehestedt, Senior Manager, Amgen, Inc.
Mona Shah, Associate Director, American Cancer Society Cancer Action Network, Inc.
Nick Shipley, Senior Director, PhRMA
Stephanie Silverman, Spokesperson, AIR 340B
Lisa Stand, Policy Associate, The AIDS Institute
Jerry Steffl, Vice President, Pharmaceutical Care Management Association
Heather Strawn, Senior Director, Federal Government Affairs, AbbVie
Susan Sumrell, Assistant Director, Regulatory Affairs, National Association of Community Health Centers
Wendy Sussman, Head of U.S. Government Affairs, Hospira
Jennifer Taylor, Manager, Federal Affairs, National Association of Community Health Centers
Grace-Marie Turner, President, Galen Institute
Ravi Upadhyay, Senior Manager, Public Policy and Reimbursement, Genentech
Keisha Vaughan, Director, The Herald Group
Anna Weinstein, Director, Federal Government Relations, BiO
Geoff Werth, Director, McKesson Specialty Health
Derrick White, Federal Government Relations, BIO
Andrew Wilson, Vice President, McKesson