



9 Carey Road, Queensbury, NY 12804 • (518) 761-0300 • www.hhhn.org

September 22, 2017

Congress of the United States
House of Representatives
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Members of the Committee on Energy and Commerce,

Please accept the enclosed briefing and response to your request dated September 8, 2017.

I think that you will find that the 340B Drug Pricing Program is absolutely essential to supporting almost everything we do as a Community Health Center to meet the needs of our rural population. We have excelled in the services we provide and are well positioned to lead new initiatives to challenges related to poverty, access to care, and cost of care in addressing the needs of the most vulnerable patients in our community.

Jim Donnelly, our Vice President of Pharmacy Services, is available by phone at 518-761-0300 ext. 34001 or by email at jdonnelly@hhhn.org.

We would be happy to provide any additional information upon request.

Sincerely,

T. Slingerland, MD

Tucker Slingerland, M.D.
Chief Executive Officer



9 Carey Road, Queensbury, NY 12804 • (518) 761-0300 • www.hhhn.org

Background Briefing Committee on Energy and Commerce September 21, 2017

Service Area: Hudson Headwaters Health Network is a Federally Qualified Health Center (FQHC) serving the large, rural and isolated Adirondack Region of northeastern New York. Incorporated as a 501c3 in 1981, Hudson Headwaters today provides comprehensive primary care and select specialty services through 17 health center sites across 5,600 square miles and 6 counties. Hudson Headwaters provides services to three distinct communities within the region: the southern Adirondack Park; greater Glens Falls; and most recently the far north including the communities along the Canadian border. In 2017, Hudson Headwaters projects that it will provide care to nearly 82,000 people through 400,000 patient encounters across a continuum of care sites including health centers, area hospitals and nursing homes, local schools, correctional facilities and patient homes.

The Adirondack Region is a very rural area, encompassing 20% of the state's land mass but less than 3% of the population. The population for Hudson Headwaters service area is 276,280. By any comparison, the Adirondack Region is sparsely populated across a very large geographic region. In addition, much of the service area population is medically vulnerable for several reasons, including: geographic isolation; a large and growing population of seniors, frail elderly and disabled; low incomes; few large employers; and transportation challenges. Of note, 30% of the population is dependent on government-sponsored health programs.

Transportation across the service area is highlighted by Interstate 87 traversing north and south with two-lane county roads running east and west. Public transportation is available only in the two small city locations below and above the Adirondack Park in Glens Falls and Plattsburgh respectively. Travel can be challenging, if not outright dangerous, during the six-month Adirondack winter.

As with many rural areas across upstate New York, the Adirondack Park Region has struggled economically on an economy built on seasonal tourism and supported primarily by small, family-owned businesses. The Adirondack Park Agency, a legislatively designated New York State Government Agency, establishes the development parameters for public and private land within the Park that typically limits large-scale economic development. The result has been a gradual decline in economic growth compounded by the emigration of the young and a resulting older population such that by 2020, the Adirondack Park region is projected to be the second oldest in the nation to Southwest, Florida.

The economic and transportation challenges, combined with an aging demographic, has severely threatened the health care delivery system across the region.

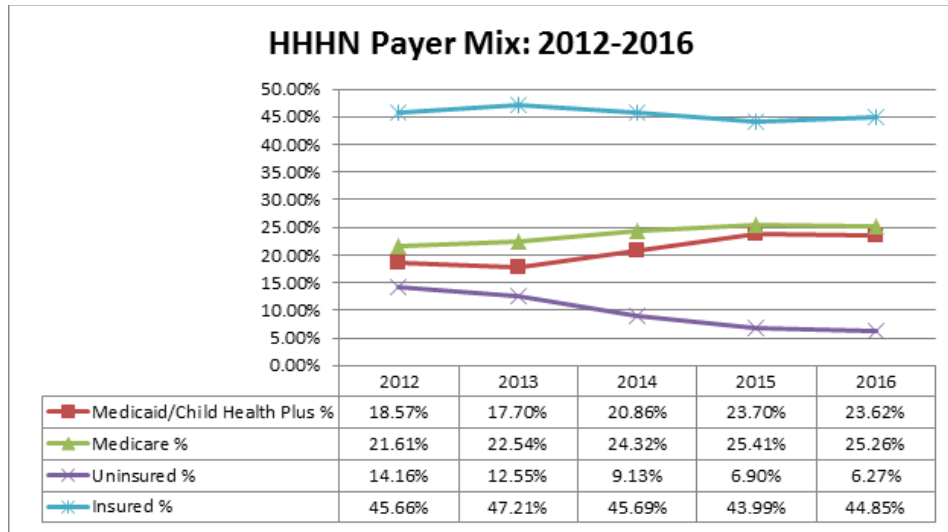
This has long been the case in the service area as market-based private practice has been unable to meet the needs of the most rural Adirondack communities. For decades, many rural towns have supported the recruitment and retention of primary care providers.

The origins of Hudson Headwaters date to the mid-1970's with the loss of the town-supported physicians in the lower Adirondack communities of Chester, Warrensburg, and North Creek. The local hospital worked with an area family practice physician, Hudson Headwaters' founding CEO John Rugge, M.D., in an attempt to stabilize access to primary care in those communities. After years of operating losses, the hospital transitioned management and ownership to a local community group that received a 330 grant as Hudson Headwaters Health Network in 1981.

Given the environment, it is not surprising that there is a shortage of health care providers in our service area as suggested by the designation of much of the area as a Health Professional Shortage Area. In the lower Adirondack Park region, Hudson Headwaters' market share is 85% - 90%, indicating a clear lack of other providers. While many private primary care practices are closing, the few that remain often either do not participate in government-sponsored insurance programs or do not have the capacity to increase access for these patients - despite the fact that the number of Medicare and Medicaid patients in our service area is increasing significantly.

Patient Population: Hudson Headwaters' patient panel of close to 82,000 accounts for 30% of the total service area population. Compared to the service area, Hudson Headwaters manages a patient panel that is older still, with 25% of our patients over age 65 and nearly 6% over the age of 80. (This compares to the national FQHC average of 9% Medicare and service area of 15%.) In addition, almost a quarter of our patients are covered by Medicaid (compared to 14% overall in our service area.) Finally, our patients are of relatively modest income and educational means, and are more likely to face transportation challenges.

Payer Mix: In the Adirondack region, much of the recent coverage expansion has transitioned low-income, working families from the ranks of the uninsured to managed Medicaid plans. As shown below, Hudson Headwaters has greatly expanded access to Medicaid and Medicare patients, who often have difficulty finding providers willing to accept their insurance in our service area.



Role & Mission: Hudson Headwaters is a FQHC with a mission to provide “the best healthcare and access to that care, for everyone in our communities”. As outlined above, much of the service area population is vulnerable due to access, age, disability, income, transportation barriers, and reliance on government health programs.

As a FQHC, Hudson Headwaters provides care to every patient, regardless of insurance status or ability to pay, and charges based on a patient’s ability to pay. In its 36-year history, Hudson Headwaters has never once denied care or discharged a patient for lack of payment.

Hudson Headwaters patients who are uninsured or underinsured and who have incomes below the Federal Poverty Level (FPL) receive all medical services and prescription drugs free of charge. In 2016, roughly one-quarter of our patients fell into this category. Patients who are between 101% and 200% FPL -- another 30% of our patients -- are charged on a sliding fee scale based on income. (See Question 4 for details on income brackets and level of discounts.) If a person has insurance, but their out-of-pocket costs (e.g., for deductibles or copays) would be higher than what they would pay under the sliding fee scale, Hudson Headwaters charges them only the discounted amount.

Approximately 45% of our patients have incomes above 200% FPL, but for reasons discussed above would still be medically underserved if Hudson Headwaters were not in the area. In this large and rural service area, Hudson Headwaters has filled the void created by a collapsing private practice primary care, the financial challenges of area hospitals and the overall economic and demographic changes that are endemic to the region. Hudson Headwaters has sought to address the area’s health care needs with a commitment to leadership, innovation, and collaboration in support of patient access, rural medicine and advanced primary care. Hudson Headwaters has also been a leading proponent of population health and the need to transition the health care delivery system from hospital-centered and fee for service reimbursement to patient-centered with value based contracting.

Hudson Headwaters has utilized funding from patient care operations, private and government payers, HRSA's Community Health Center program, local municipalities, the New York State Department of Health, private foundations and the 340B program to develop a nationally recognized rural model of care. While all funding supports the mission, most of the funding streams are designed to assure Hudson Headwaters' stable presence in the medically underserved Adirondack Park region. While critical, such funding barely provides for annual operating margins let alone the working capital to meet the access needs of an expanded region or the investments required to lead the transition to population health.

Oversight and Program Requirements that apply to all FQHCs: As an FQHC, Hudson Headwaters is subject to intensive oversight by HRSA to ensure our on-going compliance with the 18 Program Requirements. This oversight takes many forms, including: site visits; mandatory annual reporting on budget, patient, and quality measures (which are posted publicly on the HRSA website); frequent contact with our Project Officer; and regular re-competitions for grant funding.

In addition, we are required by statute to reinvest all 340B savings into activities that are approved by HRSA and advance our mission of expanding access to quality care to medically underserved populations.

340B Program: Without the 340B program, Hudson Headwaters could not have significantly expanded regional access to an advanced model of primary care; created new and expanding student and resident teaching programs in collaboration with academic medical centers; developed and financially supported crucial innovative care management programs in support of population health; and developed an infrastructure based on nationally recognized best practices that have provided the foundation in support of the mission. While these uses of 340B savings will be discussed further in Question 3, we provide a brief overview of our 340B program here:

- Reliance on contract pharmacies to expand access and avoid competing with local businesses: Hudson Headwaters has strategically chosen to use only contract pharmacies in our 340B system. This decision is based on several factors, including:
 - Maximizing access for our patients. Given our large, rural, and mountainous service area, and the difficulties in travel (particularly during the long winters) contract pharmacies allow our patients to access drugs much closer to home, and often during more accessible hours than if they had to come to a Hudson Headwaters site.
 - Reducing costs and administrative concerns for Hudson Headwaters. The costs and efforts of developing in-house pharmacies would be extensive, including maintaining inventory, recruiting pharmacists. Relying on contract pharmacies allows us to avoid these expenses.
 - Not competing with local businesses, including some small "mom and pop" operations. Hudson Headwaters provides extensive oversight of its contract pharmacies, to assure that there is no diversion of 340B drugs and that patients are charged the appropriate discounted rates. This oversight includes monthly internal audits of transactions from

each pharmacy site, annual audits by an independent audit firm, and a HRSA 340B audit, conducted in 2015, with no adverse findings.

- All drugs - both those purchased under 340B and others - are provided free of charge to all uninsured/underinsured persons under 100% FPL, and on a sliding fee scale for uninsured/underinsured persons between 101% and 200% FPL: See question 4 for further details, including a chart showing the level of discounts by income class for persons between 101% - 200% FPL. Also, it is important to note that while Hudson Headwaters does not purchase generics under 340B, it applies the sliding fee discounts to all generics as well as brand drugs.
- Despite a focus on prescribing generics, Hudson Headwaters' 340B purchases are limited to brand-name drugs: Though Hudson Headwaters' medical staff prescribes generics at a rate above the national average, 88.2% compared to a national rate of 84.6% in 2016, with a few exceptions, the organization has chosen to limit its 340B program to brand drugs. From a financial perspective, the 340B savings that can be achieved for many generic drugs do not justify the costs of the inventory management and extensive tracking and auditing systems inherent in a well-managed 340B program.
- Factors that make Hudson Headwaters different from a typical health center: Hudson Headwaters has several characteristics that make us different from a "typical" health center, and that impact the types of drugs we can purchase and our ability to retain 340B savings (as opposed to passing them directly onto patients.) These characteristics include:
 - Larger percentage of Medicare patients. While Medicare patients account for roughly 9% of health center patients nationwide, they account for 25% of Hudson Headwaters' patients.
 - Larger percentage of patients above 200% FPL. On average, 8% of health centers' patients have incomes above 200% FPL; for Hudson Headwaters, this percentage is 46%.
 - Special permission from HRSA to provide a few select specialty services. In rare cases where the patients in a service area have a clear need for a specific type of specialty service, and this type of service is not available from other providers, HRSA may allow a health center to provide this service under its "scope of project." Because of the shortage of select specialty services in the Adirondack region, Hudson Headwaters has approval to provide such services. (For more information on the criteria that must be met in order to receive HRSA approval to provide specialty services under a health center's scope of project, please see Policy Information Notice 2009-02, "Specialty Services and Health Center Scope of Project", available at <https://bphc.hrsa.gov/programrequirements/policies/pin200902purpose.html>)

HUDSON HEADWATERS HEALTH NETWORK

Data Request

Committee on Energy and Commerce

September 21, 2017

1a. The Number of 340B drugs your organization, and all associated sites and off-site outpatient facilities registered as child sites, purchased for that year. Please provide a breakdown of the number of these drugs that were purchased by the covered entity's child sites and the number directly purchased by the covered entity.

In this and the following questions, the number of drugs represents all of the 340B purchases from the contracted pharmacies for the requested years. The numbers represent individual 11-digit National Drug Codes (NDC) which denotes specific package sizes accumulated and replenished into the contract pharmacies.

Number of 340B Drugs Purchased 2012 - 2016

Year	2012	2013	2014	2015	2016
#of 340B Drugs Purchased	2,149	1,477	1,854	1,433	1,197

Note: Data reflects count of unique NDCs (National Drug Code's for each drug including specific package information as purchased).

All of Hudson Headwaters' 340B drugs are purchased by and billed to our parent organization at our administrative office location. The drugs are shipped to each contracted pharmacy via a "ship-to bill-to" arrangement. Each pharmacy site has individual accumulations and exclusive wholesaler accounts specific to the 340B registration.

1b. The percentage of 340B drugs purchased and dispensed that fall into each of the following categories.

Drug Category Percentages: 2012 – 2016

Drug Category	2012	2013	2014	2015	2016
Analgesics	2.60%	0.92%	0.95%	0.45%	0.51%
Antidepressants	8.26%	8.06%	2.84%	1.38%	1.65%
Oncology Treatment Drugs	0.04%	0.03%	1.87%	3.04%	2.94%
Antidiabetic agents	14.70%	18.03%	18.63%	22.68%	24.01%
Antihyperlipidemic agents	3.83%	4.63%	4.57%	4.13%	2.56%
Other Categorization	70.58%	68.34%	71.14%	68.32%	68.33%

Note: Data reflects count of unique NDCs. Due to the vast majority of HHHN contract pharmacy arrangements being brand drug specific, the 340B purchases per category will not reflect HHHN generic prescriptions written and filled at participating pharmacies appropriately.

1c. The Number of 340B drugs your organization purchased that were dispensed to insured patients, including:

- i. Medicare beneficiaries**
- ii. Medicaid beneficiaries**
- iii. Commercially-insured individuals**

Purchased 340B Drugs by Payer Mix: 2012 - 2016

	2012	2013	2014	2015	2016
Medicare Part D	787	769	1223	767	825
Commercial	1675	1365	1666	931	899

Please note the following important points about this data:

- Hudson Headwaters carves out all Medicaid patients, so we have no 340B purchases for Medicaid.
- Recent decreases in unique NDC's purchased are due largely to a transition from brand-name drugs (which we purchase under 340B) to generics (which we do not.)
- The numbers reflect the count of unique NDCs.

1d. The Number of 340B drugs your organization purchased that were dispensed to uninsured patients.

Purchased 340B Drugs for Uninsured Patients: 2012 – 2016

Year	2012	2013	2014	2015	2016
Uninsured Patients	401	349	208	155	180

Note: Data reflects count of unique NDCs.

The downward trend over the past five years reflects:

- A decrease in the number of uninsured patients, due to the Medicaid expansion and increased availability of private insurance through the Marketplace.
- A shift away from brand-name drugs (which we purchase under 340B) to generic drugs (which we exclude from 340B, for financial reasons discussed above.)

1e. The Amount of Savings (in dollars), as compared to the GPO price for the same drug, that your organization generated through participation in the 340B Drug Pricing Program.

340B Savings: 2012 – 2016

Year	2012	2013	2014	2015	2016
340B Savings	\$2,985,455	\$4,876,405	\$5,060,233	\$5,355,346	\$6,625,533

Please note that several factors are considered when calculating total program savings. In particular, increased savings amounts over the past several years can be attributed to the following factors:

- An increase in the total number of patients that Hudson Headwaters is serving.
- An increase in the range of services that Hudson Headwaters is providing these patients.
- An increase in the percentage of total patient who have Medicare or private insurance.
- An increase in the cost and number of drugs.
- Increased pharmacy access for patients in areas that otherwise did not have access through expanded contract pharmacy arrangements.

1f. The amount of charity care (in dollars) that your organization provided.

And

1g. The number of patients who received charity care from your organization.

As the Subcommittee is likely aware, there is no standard definition of “charity care” for FQHCs. For purposes of this question, Hudson Headwaters defines charity care as the total value of all discounts off the cost of billable services provided to uninsured and underinsured patients with income below 200% FPL. This includes: all uncompensated or discounted medical, dental and pharmacy services.

Please note that the expansion of Medicaid and the private insurer options led to a decrease in both the dollar value and the number of patients who received “charity care” according to our limited definition. As noted above, even with increased insurance coverage among our patient population, there is still a need to develop and maintain access to ensure that vulnerable patients in this medically underserved area can find providers that accept their insurance.

	2012	2013	2014	2015	2016
Amount of charity care (in dollars) provided	\$3,639,348	\$4,247,605	\$3,819,205	\$3,170,719	\$3,006,246
Number of patients that received charity care	4,658	4,096	2,584	1,637	1,593

2. How does your organization calculate the amount of savings it generates through participation in the 340B drug pricing program? How does your organization track the amount of money your organization receives when an insured patients’ insurance reimbursement exceeds the 340B price of the drug.

Hudson Headwaters purchases 340B drugs and dispenses them to patients through contract pharmacy arrangements. The calculation of the 340B program benefit can be shown as: Total amount collected (insurance payment + co-pay or other patient payment) – (340B drug cost + dispensing fees and admin expenses)

3. How does your organization use program savings to care for vulnerable populations? Are program savings used for any other purpose?

Hudson Headwaters is a FQHC with a mission to provide comprehensive healthcare for the vulnerable population across our medically underserved service area. As outlined in the background brief, much of the service area population is vulnerable due to access, age, geography, income and reliance on government health programs. Hudson Headwater's 330 grant funding binds our organization to using the vital 340B program benefit consistent with Hudson Headwaters' mission, the Health Center program purpose and the 340B program intent to serve vulnerable patients and communities.

Hudson Headwaters uses 340B savings both to cover costs related to specific services provided to individual patients, and to develop the infrastructure – both physical and strategic/ organizational -- to ensure consistent access to high-quality, affordable care for the medically-underserved population of our rural service area. These expenses are consistent with Congress' intent for covered entities to use these savings to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Uses of 340B savings to develop and maintain the infrastructure to ensure access for the medically underserved population of our rural service area: 340B savings enable us to engage in the following activities which greatly benefit medically-underserved population of our service area:

- 1) significantly increase access to advanced primary care across the 5,600-square mile region;
 - 2) exert regional leadership towards new models of care and population health through extensive investment in care management programs;
 - 3) growing our own future medical providers; and
 - 4) develop nationally recognized infrastructure and delivery system best practices in support of the mission.
- 1.) **Expanding Access:** Hudson Headwaters first expanded beyond the original Adirondack Park sites with the alignment of three health center sites in the Glens Falls service area. These sites, established to serve the population covered under the Medicaid program, were on the verge of financial ruin. From no presence in Glens Falls in 2000, Hudson Headwaters is today the primary care home to 50% of the service area.

In subsequent years, Hudson Headwaters developed new primary care capacity in the Essex County town of Moriah (2005); the Washington County town of Fort Edward (2008), the Warren County town of Queensbury (2010) and the Clinton County town of Champlain (2012). The Network also integrated over 20 private practice primary care providers into Hudson Headwaters' sites across the region. In 2013, the network responded to a burgeoning crisis in women's health services by integrating two Glens Falls area OB/GYN practices into the network. Hudson Headwaters is

currently working with one hospital partner, the University of Vermont Health Network (UVMHN), to develop a Community Health Center site in the Clinton County city of Plattsburgh in 2019. The Plattsburgh project represents one of many initiatives implemented with UVMHN since a jointly developed 2015 Memorandum of Understanding established Hudson Headwaters as UVMHN's preferred primary care partner.

The need for expanded capacity has been addressed in partnership with area hospitals, public health agencies, private practices, HRSA and the New York State Department of Health. The resulting investment in facilities and recruitment has stabilized primary care and women's health services in the region while greatly expanding access to the most vulnerable populations including the elderly, the uninsured, those covered under the Medicaid program and high-risk patients with multiple chronic disease, mental health and/or substance abuse problems including opioid abuse. Hudson Headwaters has also partnered with area hospitals to bring select specialty services to our most vulnerable populations including fetal maternal medicine, endocrinology, neurology, and cardiology. While expanding capacity to meet the region's needs, Hudson Headwaters has grown from 12 sites serving 64,135 patients through 284,449 encounters in 2012 to 17 health center sites serving 79,471 patients via 374,323 encounters in 2016 (HRSA Uniform Data System Report).

- 2.) **Innovative Care Management:** Hudson Headwaters unique role within the regional health care delivery system encompasses much more than just physical sites and patient encounters. The Network is the acknowledged regional innovator driving the health care system towards a new model of care with a foundation of comprehensive team-based primary care with integrated behavioral health and robust care management programs.

In 2008, Hudson Headwaters led a regional effort to address the area primary care shortage. Working for nearly two years with the HRSA Office of Rural Health, Hudson Headwaters and two area hospitals developed a primary care driven innovation pilot with the New York State Department of Health that initiated as the Adirondack Medical Home Pilot in 2010. The nationally recognized all-payer Pilot (Commercial, Medicaid, and Medicare) provided care management funding to primary care practices enabling the transition to electronic medical records; an investment in robust non-billable care management programs; an expectation for NCQA Level 3 recognition and a market-based improvement in primary care compensation.

Hudson Headwaters has championed the Pilot efforts towards advanced primary care including integrated behavioral health and care management programs. Pre-Pilot, the Network's care management services were comprised of one licensed social worker, four behavioral health staff and a small home visiting program for the frail elderly. Today, Hudson headwaters provides robust care management through a staff of 70 that includes clinical nurse managers, licensed social resource advocates, expanded behavioral health including psychiatric nurse practitioners and psychologists and an expanded cadre of physicians, physician assistants and nurse practitioners.

New and expanded service programs include health center based embedded clinical nurse managers supporting small panels of patients most at risk with multiple chronic disease; clinical care nurses to help patients and families better manage the transition from hospital to home; health center embedded licensed counselors, psychiatric nurse practitioners, and psychologists to better support the immediate and ongoing behavioral health needs of our patients; and a palliative consult team available in hospital, nursing home and health center settings. Hudson Headwaters also provides services and programs targeting high-risk, vulnerable populations including a MAT program for those suffering from opioid addiction; a screening and outreach program for those at risk for Hep C; and an expanded home visit program focused on the frail and disabled, post-hospital visits and end of life care.

All Network patients and families are supported by a hospitalist and long-term care program with Network providers rounding 7 days a week/365 days a year at Glens Falls Hospital and eight area nursing homes and long-term care facilities. The Network also provides three tiers of 24-hour call specific to adult/pediatric/geriatric patient needs. The Network is also proactively engaged with patients and families through a robust website and active patient portal with over 50% of our patients routinely using the portal.

Now in its 8th year, the Pilot has transitioned to a risk model based on clinical measures, customer satisfaction scores and overall clinical costs. The transition to value-based contracting is in concert with the CMS/NYS DSRIP waiver that projects at risk contracting for the Medicaid/Managed Medicaid population by 2020. Future risks based models, up to and including global capitation, are currently being developed through the Adirondacks ACO, the region's most substantial integrated provider organization. The ACO is jointly owned by Hudson Headwaters and the University of Vermont Health Network (UVMHN) with additional human and analytic resources provided through the University's OneCare ACO; a collaborative effort between the University of Vermont Health Network and the Dartmouth Hitchcock Medical Center.

- 3.) **“Growing our own” Medical Providers:** As a key component of our efforts to recruit providers to our area, Hudson Headwaters has also collaborated with the areas two tertiary/teaching hospitals, the University of Vermont Health Network and Albany Medical Center, to extend the lessons and experiences of the advanced primary care model to their teaching programs as a valuable learning tool for students and residents. Hudson Headwaters annually hosts 18-third-year medical students from Albany Medical College on four-week rotations with Network providers. In 2017, the Network and UVMHN initiated a yearlong Longitudinal Integrated Program with the University of Vermont Larner School of Medicine providing three- third-year medical students the opportunity to follow a panel of patients for an entire year. Hudson Headwaters is also working with the UVMHN to expand their Family Practice Medicine program to include rotations through network sites as early as 2019.

The collaborative efforts with the tertiary hospitals have led to additional service, teaching and research opportunities that have benefitted patients, medical staff, and the academic medical centers. Of note are collaborations with New York City-based Mt. Sinai on screening and outreach programs for Hep C; palliative care training and consults with UVMHN; outreach fetal maternal medicine consults with Albany Medical Center and research in primary care based use of handheld ultrasound with the healthcare division of GE.

- 4.) **Best Practice Infrastructure:** In support of the mission, Hudson Headwaters has utilized 340B savings to offset the cost of developing a nationally recognized best practice operational infrastructure. In concert with the mission and vision, 340B savings have helped to establish operational margins and working capital in support of investments in human capital, health center facilities, and health information technology. The resulting investments have led to industry-leading best practices in provider recruitment and retention programs; facility development; revenue cycle operations; electronic medical records and data analytics; customer service; corporate compliance; and care management/quality programs. Hudson headwaters' experience and reputation for innovative, best practice health center operations has been a significant factor in attracting the support of our patients; local towns and counties; commercial and government payers; employers and other health care providers and community-based organizations.

Finally, in response to the question "Are program savings used for any other purpose?", Hudson Headwaters uses 340B savings exclusively for purposes that increase access to high-quality affordable care for patients in our medically-underserved service area. This approach is consistent both with our mission and with the statutory requirement that all health centers must reinvest all 340B savings into activities that are approved by HRSA and advance their mission of expanding access to quality care to medically underserved populations.

3a. Does your organization provide any additional charity care to uninsured and underinsured patients derived from sources other than the 340B Drug Pricing Program? If so, please elaborate.

Yes, Hudson Headwaters' programs in support of the most vulnerable populations also benefit through the Uncompensated Care Pool funding from the New York State Department of Health. Patients also directly benefit by Hudson Headwaters Pharmacy Assistance Program coordination where network staff, supported by 340B funding, use integrated procedures and software to assist patients across our entire network gain access to Pharmaceutical Manufacturers' Financial Assistance Programs. Our patients also benefit from sliding fee discounts made available from area hospitals and specialty practices based on Referral Agreements that Hudson Headwaters has negotiated with those providers. Finally, we receive Federal grant funding under Section 330 of the Public Health Service Act as well as Ryan White program funding.

3b. What percentage of total health care services provided by your organization is charity care?

Percentage of Charity Care: 2012- 2016

Year	2012	2013	2014	2015	2016
% of Charity Care Provided	10%	10%	8%	6%	5%

As stated in Questions 1e and 1f, there is no standard definition for “charity care” in the healthcare sector. The data we have provided reflects the total value of all discounts off the cost of billable services provided to uninsured and underinsured patients with income below 200% FPL.

4. Does your organization have any policies to ensure that uninsured and underinsured patients directly benefit from the program by receiving discounts on 340B drugs? If so, please elaborate.

Yes, Hudson Headwaters has a sliding fee program policy as required by federal regulations (42 CFR §51c.303 (f)). The regulation requires health centers to charge no more than a nominal fee for persons between 100% FPL; Hudson Headwaters provides these individuals with medical, dental services and prescriptions for free, and charges \$10 for labs and imaging services. The regulations also require health centers to create a discounted fee schedule for individuals between 101% and 200 percent of FPL (\$23,760 for an individual in 2017) but prohibit discounts for individuals above that level. The tiers are as follows:

Annual Income Ranges 2017						
	up to 100%	up to 125%	up to 150%	up to 175%	up to 200%	over 200%
	\$0 MINIMUM	\$5	\$10	\$15	\$20	NO DISCOUNT
Family Size	CATEGORY E	CATEGORY F	CATEGORY G	CATEGORY H	CATEGORY I	CATEGORY J
1	\$0-12060	\$12061-15075	\$15076-18090	\$18091-21105	\$21106-24120	> or = \$24121
2	\$0-16240	\$16241-20300	\$20301-24360	\$24361-28420	\$28421-32480	> or = \$32481
3	\$0-20420	\$20421-25525	\$25526-30630	\$30631-35735	\$35736-40840	> or = \$40841
4	\$0-24600	\$24601-30750	\$30751-36900	\$36901-43050	\$43051-49200	> or = \$49201
5	\$0-28780	\$28781-35975	\$35976-43170	\$43171-50365	\$50366-57560	> or = \$57561
6	\$0-32960	\$32961-41200	\$41201-49440	\$49441-57680	\$57681-65920	> or = \$65921
7	\$0-37140	\$37141-46425	\$46426-55710	\$55711-64995	\$64996-74280	> or = \$74281
8	\$0-41320	\$41321-51650	\$51651-61980	\$61981-72310	\$72311-82640	> or = \$ 82641
9	\$0-45500	\$45501-56875	\$56876-68250	\$68251-79625	\$79626-91000	> or = \$ 91001
10	\$0-49680	\$49681-62100	\$62101-74520	\$74521-86940	\$86941-99360	> or = \$99361
Pharmacy	\$0	\$5	\$10	\$15	\$20	0%
Lab/Imaging	\$10	87%	78%	69%	60%	0%
Dental	\$10	\$23	\$33	\$43	\$53	NO DISCOUNT

Thus, as stated in our introductory briefing:

- Uninsured and underinsured persons with incomes at or below 100% FPL receive all drugs (including those dispensed outside 340B) for free.
- Uninsured and underinsured persons between 101% and 200% FPL are charged for drugs based on a sliding fee scale based on income and family size (regardless of the price of the drug.) As indicated on the chart above, the charges range from \$5 to \$20.
- Persons with incomes above 200% FPL are not eligible for discounts.

5. How many child sites does your organization have registered to participate in the 340B Drug Pricing Program? Please provide a list of all child-sites, including the location of the Child-site and the date it began participating in the program.

As of December 31, 2016, Hudson Headwaters had 18 child sites registered to participate in the 340B Drug Pricing Program. The list and chart below show the number of registered child sites from 2012-2016.

Participating Start Date	Entity Sub-Division Name	Address	City	State	Zip	Billing Address
4/1/2001	ADMINISTRATION	9 CAREY ROAD	QUEENSBURY	NY	12804	9 CAREY ROAD
4/1/2001	CHESTER HEALTH CENTER	6223 STATE ROUTE 9	CHESTERTOWN	NY	12817	9 CAREY ROAD
4/1/2001	NORTH CREEK HEALTH CENTER	126 SKI BOWL RD	NORTH CREEK	NY	12853	9 CAREY ROAD
4/1/2001	INDIAN LAKE HEALTH CENTER	6356 NYS ROUTE 30	INDIAN LAKE	NY	12842	9 CAREY ROAD
4/1/2001	BOLTON HEALTH CENTER	11 CROSS STREET	BOLTON LANDING	NY	12814	9 CAREY ROAD
4/1/2001	SCHROON LAKE HEALTH CENTER	24 FAIRFIELD AVENUE	SCHROON LAKE	NY	12870	9 CAREY ROAD
4/1/2001	TICONDEROGA HEALTH CENTER	102 RACE TRACK ROAD	TICONDEROGA	NY	12883	9 CAREY ROAD
4/1/2001	WARRENSBURG HEALTH CENTER	3767 MAIN STREET	WARRENSBURG	NY	12885	9 CAREY ROAD
1/1/2007	MORIAH HEALTH CENTER	33 TOM PHELPS LANE	MINEVILLE	NY	12956	9 CAREY ROAD
4/1/2001	HEALTH CENTER BROAD	100 BROAD STREET	GLENS FALLS	NY	12801	9 CAREY ROAD
4/1/2001	MOREAU FAMILY HEALTH CENTER	1448 ROUTE 9	SOUTH GLEN FALLS	NY	12803	9 CAREY ROAD
4/1/2001	QUEENSBURY FAMILY HEALTH CENTER	14 MANOR DRIVE	QUEENSBURY	NY	12804	9 CAREY ROAD
8/15/2011	FT EDWARD-KINGSBURY	48 EAST STREET	FORT EDWARD	NY	12828	9 CAREY ROAD
7/1/2012	WEST MOUNTAIN HEALTH CENTER	161 CAREY ROAD	QUEENSBURY	NY	12804	9 CAREY ROAD
10/1/2012	CHAMPLAIN HEALTH CENTER	828 STATE ROUTE 11	CHAMPLAIN	NY	12919	9 CAREY ROAD
10/1/2013	NORTH COUNTRY OB/GYN	90 SOUTH STREET	GLENS FALLS	NY	12801	9 CAREY ROAD
10/1/2014	TUCKER CLINICAL SERVICES	3761 MAIN ST	WARRENSBURG	NY	12885	9 CAREY ROAD
1/1/2016	HEALTH CENTER BROAD	118 BROAD ST	GLENS FALLS	NY	12801	9 CAREY ROAD
1/1/2002	RYAN WHITE PROGRAM	1 BROAD ST PLAZA	GLENS FALLS	NY	12801	9 CAREY ROAD

As stated in Question 1a, all 340B purchasing is done through our “parent” organization, at the main administrative site.

6. How many pharmacies has your organization contracted with to dispense drugs purchased through the 340B Drug Pricing Program on your behalf?

As of December 31, 2016, Hudson Headwaters contracts with 8 pharmacies covering 38 locations contracted to participate in the 340B Drug Pricing Program. The table below shows the number of contracted pharmacies from 2012-2016.

Hudson Headwaters Contract Pharmacies		
Year	Unique Contracts	Unique pharmacies
2012	6	23
2013	7	26
2014	8	31
2015	7	34
2016	8	38

- While the number of unique contracts has remained relatively stable during the past 5 years, the number of pharmacy sites has increased as pharmacy operators have opened more sites within our service area.
- Hudson Headwaters service area has grown from 4,000 square miles to 5,600 square miles creating the need for more pharmacy access.
- The addition of new pharmacy sites has increased access to pharmaceuticals for medically underserved patients – particularly those facing transportation challenges, including those that result from challenging winter weather.

6a. Do your contracts with these pharmacies require that program savings be passed on to the intended beneficiaries, including requiring that uninsured or underinsured patients receive discounts on 340B drugs?

Yes. All contracted pharmacies are required to participate (be in-network) with the PBM which adjudicates our sliding fee program. As discussed in Question 4, uninsured and underinsured persons with incomes below 100% FPL are provided all drugs (both those purchased under 340B and others) free of charge; persons between 101% and 200% FPL are charged based on a sliding fee scale.

6b. Does your organization share any program savings with these contract pharmacies? If so, please elaborate.

No, Hudson Headwaters only pays fair market value for the services provided. The payments to the pharmacies are negotiated to represent the pharmacies' actual margin if the dispensing drug was not 340B eligible, with an additional add-on for the involvement of 340B integration such as inventory management and data exchanges. Each pharmacy requires a separate negotiation based on the drug mix captured through the pharmacy and the pharmacy business rules. No sharing of the 340B benefit is part of any contract.