

Cook Area Health Services, Inc.
Response to Energy and Commerce Committee
Chairmen Walden and Murphy
September 22, 2017

Cook Area Health Services, Inc. (CAHS) is a 38-year-old Community Health Center providing primary health care, oral health, behavioral health, and pharmacy services, to a large sparsely populated area in northern Minnesota. CAHS sees more than 12,000 patients each year. Almost half of our patients live in families with incomes below the Federal Poverty Level (FPL). About 18% of patients are uninsured, and the one-third who have private insurance are often underinsured. We offer our full range of service to every individual, regardless of ability to pay, and charge based on a sliding fee scale.

Our service area is approximately 8300 square miles and has a population of 24,944 (*US Census 2010*). It has a population density of 3 people per square mile. The service area stretches across four counties and contains 98 small towns and townships. It is slightly smaller than the state of New Jersey. The Federal government has designated our service area in its entirety as Medically Underserved. It contains seven separate Medically Underserved Area/Populations Designations and fourteen Health Professional Shortage Area Designations. They are MUA/P ID#s 01640, 01682, 07062, 07331, 01681, 01671 and 04040. The four medical HPSAs are ID# 1279992706, 1279992728, 1279992796 and 12799927K6. The six dental HPSAs are ID# 6279992709, 6279992753, 6279992755, 6279992707, 6279992730 and 6279992729. The four mental health HPSAs are ID# 7279992704 (Itasca, Koochiching and St. Louis Counties) and 7279992756 (Beltrami County).

CAHS operates six medical clinics and four dental clinics. We are the only primary care providers in our core service area.

The area population is frontier, remote, isolated and sparsely populated. It is in the northeast region of Minnesota and includes northern St. Louis County, northern Itasca county, all but the northeast corner of Koochiching county and a portion of eastern Beltrami County. The area is located approximately 225-300 miles north of the Minneapolis/St. Paul metropolitan area.

Currently many of our patients travel from 35 to 55 miles over secondary roads to reach our sites that offer primary medical care. Our sites are dispersed across the area and are located in towns that have fewer than 600 people. These are the largest towns in the core service area. Northern Minnesota has long, cold winters when annual snowfall usually exceeds 100 inches and temperatures can drop to -60°F. This makes travel difficult, hazardous, and often impossible. Since roads are in poor shape, emergency medical responders find accessibility challenging and often take over an hour or more to reach an emergency or crisis. No public transportation is available in the area.

Provision of pharmacy services in this area is as challenging as the provision of medical, dental and behavioral health services. There are only two retail pharmacies in the primary CAHS service area. Both are located in the communities that have Critical Access Hospitals. The first is Franks Pharmacy in Cook, MN. It is a long standing, small town pharmacy. The second is the Bigfork Valley Pharmacy in Bigfork, MN. It is operated by the Bigfork Valley Hospital. The Critical Access Hospital started this retail pharmacy after the local pharmacy closed. Two of our other medical site communities had retail pharmacies, but they both closed approximately 20 years ago.

Over the years, CAHS has considered adding retail pharmacy services. We have not been able to justify this addition for a number of reasons. Our medical clinic facilities do not have sufficient space to meet licensing

requirements. There is also a significant shortage of pharmacists in the region and they can be more difficult to recruit to the area than physicians. In addition, our communities are small and the projected prescription volumes are low. These factors indicate a lack of financial viability for the service.

As a Community Health Center, Cook Area Health Services, Inc. is eligible to participate in the 340B Drug Pricing Program and is a “covered entity”. CAHS began participation in the 340B Program on January 1, 2003. We entered into a contract with RxStrategies, Inc. for 340B Program management and with Bigfork Valley Pharmacy as our contract pharmacy.

RxStrategies provides 340B administrative services for Covered Entities, and provides the QE with the ability to manage and maintain a compliant 340B program. RxStrategies administrative systems and solutions include transparent identification of script eligibility and reporting of the 340B program with a virtual accumulation system. RxS tracks dispensations and facilitates replenishment on behalf of the CE for the contract pharmacies enrolled in the 340B program as deemed eligible by HRSA and the OPA.

RxStrategies enhanced compliance focus provides Covered Entities with tools such as Compliance Plus, the 340B Plus Portal, and the RxStrategies 340B Analytics Tool which allows Covered Entities the ability to track and monitor every aspect of their program in order to remain in the forefront of compliance. RxStrategies also provides dedicated account management and executive sponsorship to ensure each account operates efficiently and to the expectations of the Covered Entity as intended by HRSA and the Office of Pharmacy Affairs.

The 340B Drug Pricing Program is important to us because it helps us deliver pharmacy services to our patients and is an important tool in the provision of prescription drugs to our low income patients.

1. In a chart or similar format, please list each of the following items for 2012, 2013, 2014, 2015 and 2016.

- a. 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;**

	2016	2015	2014	2013	2012
Number of 340B Drugs	12,340	11,547	7,317	7,526	7,134

All 340B drugs were purchased with our main organization as the covered entity and none were purchased by our child sites.

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

Therapeutic Class	2016	2015	2014	2013	2012
i. Analgesics	0.0%	0.0%	1%	2%	2%
ii. Antidepressants	0.0%	0.0%	0.6%	1.20%	2.40%
iii. Onco Drugs	0.0%	0.4%	0.0%	0.0%	0.0%
iv. Antidiabetic	20.5%	19.1%	21.0%	18.3%	16.8%
v. Antihyperlipidemic agents	2.4%	4.0%	3.0%	5.0%	9.0%

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

Patient Type:	2016	2015	2014	2013	2012
Medicare:	2,321	1,481	1,522	1,604	1,015
Medicaid:	0	0	0	0	0
Commercial:	11,158	10,263	5,725	5,462	4,988

- d. The number of 340B drugs your organization purchased that were dispensed to uninsured patients:

Year:	2016	2015	2014	2013	2012
340B drugs for uninsured:	1,182	1,284	1,592	2,064	2,146

- e. 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; and:

Year:	2016	2015	2014	2013	2012
Savings 340B vs GPO	\$207,808	\$124,322	\$83,430	\$100,409	\$82,477

- f. The amount of charity care (in dollars) that your organization provided; and

Year:	2016	2015	2014	2013	2012
Charity care provided by covered entity re: 340B:	\$5,151	\$5,207	\$7,943	\$12,506	\$14,758
Charity care provided by covered entity:	\$1,773,077	\$1,507,877	\$1,599,487	\$1,551,308	\$1,487,015

The first category is the value of the dispensing discounts provided under our sliding fee scale for our uninsured and underinsured patients. Current software does not provide us with the ability to calculate the value of the discounts from GPO pricing to 340B pricing. The second category is the amount of charity care provided by the organization for all other services.

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

Year:	2016	2015	2014	2013	2012
Number of charity care patients re: 340B:	743	644	1,078	1,605	1,834
Number of charity care patient for organization	2,246	1,978	2,185	2,823	3,542

2. How does your organization calculate the amount of savings it generates through participation in the 340B Drug Pricing program?

CAHS only records the net between 340B program revenue less 340B acquisition cost and dispensing fees in its financial statements.

How does your organization track the amount of money your organization receives when an insured patients' insurance reimbursement exceeds the 340B price paid for the drug?

The organization receives semi-monthly statements from our 340B Drug Pricing program contract administrator, Rx Strategies. These statements identify direct purchase costs as well as the amount of money the organization receives when the insured patients' insurance reimbursements exceed the total of the 340B price and dispensing fees.

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

CAHS passes the full 340B savings directly to all uninsured and underinsured patients, who are charged only the 340B price for their drugs.

340B savings are also used in a number of other areas within the organization. For example:

- To implement an aggressive Opioid Reduction Program, focusing on both patients and providers. CAHS is also committed to improving the quality of pharmacy services to our patient population. Northeastern Minnesota has the highest quantity of opioids prescribed per capita in the state of Minnesota with the highest rate of opioid overdoses between 1999 and 2014. Since January 2015, CAHS has worked with its staff to enhance knowledge regarding opioid prescribing and to assist in the appropriate management of individual chronic pain patients. Strong commitment from medical providers, case management RN's and support staff has made this program successful with a dramatic reduction in opioid use for the CAHS chronic pain patient population. An Opioid Prescription and Refill Management Guideline (OPRMG) was implemented in 2015 in our Cook, MN site based on guidelines and recommendations from the Institute for Clinical Systems Improvement (ICS), the Center for Disease Control (CDC) as well as the morphine dose equivalence as set by the Minnesota Department of Health and Minnesota Medical Assistance Program. The OPRMG is updated annually and utilized by prescribing medical providers when managing patients with chronic pain. In February, 2015, 42% of

CAHS chronic patients were at the appropriate morphine dose equivalence (MDE) of less than 120 based on OPRMG recommendations.

CAHS tracked 134 patients who were identified at one clinic site being treated with opioids to manage chronic pain. 58% of these patients were over goal with a MDE of greater than 120. Of these patients over 30% were on a daily MDE greater than 500 mg a day. The high incidence of opioid use was significant and reinforced the need for patient safety initiative.

Through ongoing efforts and direction of the Chief Medical Officer, the Chief Operations Officer, the support of our medical providers, reduction scheduling by a consulting pharmacist and RN case management for this identified patient population, reduction in opioid use was accomplished. A slow and gradual reduction in opioid use was achieved. By March, 2016, 49% of patients were over goal which was a reduction of 9% in one year. CAHS chronic pain management program continued through 2016 with a noted decrease in number of patients on opioids. In January, 2017, the chronic pain patient panel had decreased from 134 originally to 100 patients. Opioids had been eliminated from treatment plans for some patients. Only 15% of patients were over the 100 MDE goal. This is a notable reduction improvement of 43%. 85% of this patient population was now at goal. There were no patients at an MDE of greater than 500, compared to greater than 30% of patients greater than 500 MDE in 2015.

In January 2017, MDE goal was changed to meet CDC's latest best practice of 100 MDE. In addition the goal was lowered to 50 MDE for any patient who was on a concomitant benzodiazepine. Additional CAHS clinic sites were brought into the CAHS chronic pain management program in January, 2017. Baseline data identified these clinic sites with at 85% goal compliance of MDE less than 100. Utilization of established resources through the CME, COO, medical providers, consulting pharmacist and RN case managers provided further opioid reduction efforts across all clinic sites.

By June, 2017 only 89 of the original 134 patients were either on opioids or currently receiving chronic pain management by CAHS. Of this original patient panel 83% were at new goal of less than 100 MDE. Other clinic sites identified 92% of chronic pain patients at goal in June, 2017.

In June, 2017, CAHS chronic pain total patient population was represented by a total of 175 patients in all six CAHS medical sites, of which 86% were at goal of MDE less than 100. Efforts will continue moving forward with chronic pain management and is an ongoing Quality Improvement measure for CAHS.

Resources utilized to support the CAHS Opioid Reduction Program included extensive time from the medical director and the chief operations officer. A consulting pharmacist was hired to review chronic pain patients' prescriptions, calculating morphine dose equivalence and recommending dosing reductions. Medical providers were actively involved in setting reduction targets and required additional time with patients to implement and enforce the reduction program. Daily support by RN case management nurses was provided to assist with prescription management utilizing the Minnesota Prescription Monitoring Program, completing random urine drug screens, pill counts, and patient education regarding the risks of opioid use and benefit of reduction. Resources will continue to be used through CAHS clinic sites to educate providers and staff on ongoing reduction program guidelines and management of the chronic pain population. Protocols and procedures in place will be ongoing and monitored on a regular basis. Additional resources to support behavioral health integration and assist with substance abuse counseling are pending implementation in fourth quarter of 2017.

The costs of this opioid reduction program were approximately \$200,000 in 2015 and \$230,000 in 2016. CAHS did not receive any additional grant funding for this activity and used savings from the 340B program to partially offset the program cost.

- To support the costs of operating an automated, direct to patient prescription dispensing system. Four of our medical clinics are located in communities which do not have a retail pharmacy. Our clinic in Tower, MN is more than 20 miles from the closest pharmacy. In order to improve the access to pharmacy services to the community, CAHS has installed an automated, direct to patient prescription dispensing system. This system, provided under a contract with InstyMeds, dispenses prepackaged prescriptions with an electronic prescription order. The automated system, which is much like an ATM, is stocked with 30 common prescription items. The system is NOT stocked with items purchased through the 340B program. This clinic is usually staffed with one nurse practitioner or physician's assistant. The clinic is small and prescription volumes are low and the cost of providing this basic access to prescriptions requires a subsidy.
- To cover the costs associated with dispensing drug samples to patients. CAHS still maintains a drug sample inventory for distribution to patients by CAHS providers. These samples are provided at no charge to the patient, however there is a resulting cost to the organization to maintain samples, record their dispensing within our EHR and dispose of expired samples. CAHS uses 340B savings to help cover these costs. Approximately 300 patients per year receive samples.
- To assist patients completing applications for the pharmaceutical manufacturers Patient Assistance Programs. We assist about 60 patients per year in completing new applications. We are unable to calculate the number of patients receiving ongoing program assistance as the pharmaceutical manufacturers then interact directly with the patients receiving assistance. We believe that there are more than 200 patients receiving direct assistance from the pharmaceutical manufacturers as a result of these efforts.
- To cover the costs of dispensing drugs at 340B prices to uninsured and underinsured patients: As stated earlier, CAHS passes the full 340B savings directly to uninsured and underinsured patients, by charging them only the purchase price for the drug. The 340B savings from drugs dispensed to other patients are used to help offset the cost of dispensing drugs for these patients.

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

As an FQHC, CAHS is required to charge no more than a nominal fee for services provided to patients with incomes below 100% FPL, which is about 46% of our patients. For patients between 101% to 200% FPL (about 48% of our patients), we charge using a sliding fee scale based on income. Even if a person has insurance, we charge only them the sliding fee scale amount if that is less than what their insurance would charge.

To help offset these costs, Cook Area Health Services, Inc. receives grant funding under the Community Health Center Program (Section 330 of the Public Health Services Act).

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

	2016	2015	2014	2013	2012
Charity Care %	15%	14%	15%	16%	12%

This percentage does not include bad debt or undercompensated care payments from Medicare, Medicaid or commercial insurers.

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

Scenic Rivers has a sliding fee scale discount policy that applies to all patients with incomes at or below 200% of the federal poverty guidelines. As a component of our sliding fee scale, patients below 200% FPL are able to get pharmacy prescriptions at the 340B price. Scenic Rivers also has a policy on credit and collections that all patients, regardless of their ability to pay, will be treated equally and give the ability to pay for their services as appropriate for their individual circumstances. These policies allow for patients to directly receive discounts related to 340B drug purchases.

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.

Grant Number	Site ID	340B ID	Entity Type	Participating Start Date	Entity Name	Entity Sub-Division Name	Address 1	City	State	Zip	Second Zip
H80CS00706	BPS-H80-005619	CH052710	CH	1/1/2003	COOK AREA HEALTH SERVICES, INC.	SCENIC RIVERS HEALTH SERVICES	20 5th St SE	Cook	MN	55723	9702
H80CS00706	BPS-H80-001383	CH05271B	CH	1/1/2004	COOK AREA HEALTH SERVICES, INC.	SCENIC RIVERS HEALTH SERVICES	135 PINE TREE DR	BIGFORK	MN	56628	0135
H80CS00706	BPS-H80-001833	CH05271C	CH	1/1/2004	COOK AREA HEALTH SERVICES, INC.	SCENIC RIVERS HEALTH SERVICES	12052 MAIN STREET	NORTHOME	MN	56661	0066
H80CS00706	BPS-H80-017777	CH05271D	CH	1/1/2004	COOK AREA HEALTH SERVICES, INC.	SCENIC RIVERS HEALTH SERVICES	810 Poplar Street	FLOODWOOD	MN	55736	
H80CS00706	BPS-H80-006941	CH05271F	CH	1/1/2004	COOK AREA HEALTH SERVICES, INC.	SCENIC RIVERS HEALTH SERVICES	410 2ND STREET, NW	BIG FALLS	MN	56627	0218
H80CS00706	BPS-H80-012621	CH05271G	CH	7/1/2014	COOK AREA HEALTH SERVICES, INC.	Scenic Rivers Health Services	415 North Second Street # 2	Tower	MN	55790	

All 340B purchases are made under the 340B ID CH05271D.

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

Two. The contract with Jon's Drug has not been executed by the pharmacy.

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

Yes. Patients who are uninsured or underinsured are able to receive drugs at the 340B price. CAHS covers the costs of dispensing these drugs using the savings accrued from dispensing 340B drugs to insured patients.

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

No. The contract pharmacy is paid a fixed dispensing fee. That fee is \$9.00 per generic and \$15.00 per legend prescription.