

LYNN A. WESTMORELAND
3RD DISTRICT, GEORGIA

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Congress of the United States
House of Representatives
Washington, DC 20515-1003

COMMITTEES:

FINANCIAL SERVICES
VICE CHAIRMAN, SUBCOMMITTEE ON
INSURANCE, HOUSING, AND
COMMUNITY OPPORTUNITY
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CHAIRMAN, SUBCOMMITTEE ON
NSA AND CYBERSECURITY

DEPUTY WHIP

October 13, 2016

The Honorable Jim Macrae
Acting Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Administrator Macrae:

We are writing to express our concerns with the Redesigning Liver Distribution proposal that was published in August 2016 for public comment. This proposal would have a negative impact on liver transplant candidates in Georgia and the Southeastern region overall. Specifically, the proposed redistricting would reduce the number of liver transplants performed in Georgia by a minimum of 20%, further exacerbating the existing inequalities in health in our region and increasing the number of preventable deaths in this state.

In the last year, Georgia donors generously gave 246 livers for transplant. Of those, more than 170 were transplanted by in-state centers, and an additional 57 were used in the Southeast region. Over the same period, Georgia hospitals performed 253 liver transplants, with recipient survival above that predicted by risk-adjusted algorithms. Our state's success in realizing the benefit of liver transplant is a testament to the cooperation and trust that we have built within our community. With several high performing transplant centers in Georgia, we are justly proud of the many successes that liver transplantation has achieved in our state.

Importantly, there is an additional subset of Georgians that we believe will shoulder the burden of this proposed allocation policy. As written, this policy will have a significant, unforeseen negative impact on Georgia's children. In the state of Georgia, the Emory University/Children's Healthcare of Atlanta (CHOA) collaborative liver transplant program is the sole provider of pediatric liver transplant services. This program is nationally recognized as the third largest pediatric liver transplant center by volume and serves Georgia's neediest children. Approximately 60% of CHOA's liver transplant recipients are insured by Georgia Medicaid and over 40% are from rural Georgia and outside the metropolitan Atlanta area. Furthermore, well over 30% of these recipients are of African American or Hispanic descent which is roughly double the proportion of recipients when compared with other regions of the country.

For adult patients, Emory University and Piedmont Healthcare provide all liver transplantation services in the state. Compared to the Northeast, the Southeast has a significantly higher laboratory MELD score at the time of transplant. In the Northeast, nearly 40% of patients

receive MELD exception points. This artificially increases the MELD score required for transplant by those patients who do not qualify for MELD exception points. In sum, adult patients in the Southeast typically have higher MELD scores and therefore may be at higher risk of death without transplant than patients in the Northeast.


Importantly, executing this policy will impose a significant burden on the nation. Wider organ distribution will greatly increase the logistic complexity and financial costs of donation. For instance, excess payments for travel alone would amount to at least \$15 million per year. These costs will be passed onto Medicare, Medicaid, and third-party insurers further increasing the price of, and reducing access to transplantation. Additionally, opportunities for transplant will be lost, with best-case estimates of at least 2% fewer livers available nationally per year *according to the proposal's own sponsors*. This combination of increased cost and reduced benefit runs directly counter to the mandates of the HHS Final Rule.

We respectfully request that UNOS abandon the current Redesigning Liver Distribution policy, and we pose the following questions:

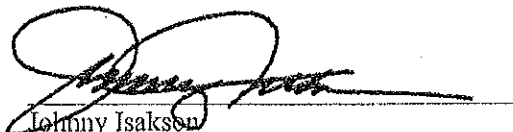
1. Which entity among HRSA, OPTN, and UNOS is responsible for reviewing public comment and making modification to the proposal?
 - a. What factors will be taken into account in the review to impact these decisions?
2. Will this proposal go through a formal rule-making process? If not formal rule-making, where in statute is the authority for this proposal?
3. Has a state by state analysis been done to evaluate the prospective impact on patient?
 - a. What is the impact on Georgia transplant patients?

Furthermore, we ask that no policy be enacted that would worsen access to life-saving liver transplantation for high-risk patients or would increase the complexities and costs of donation. Thank you for your consideration of our comments and for the work that you have done, and continue to do, for liver transplant patients across the country.

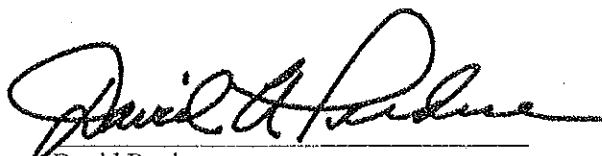
Sincerely,



Lynn A. Westmoreland
Member of Congress



Johnny Isakson
United States Senator



David Perdue
United States Senator

Earl L. 'Buddy' Carter

Earl L. "Buddy" Carter
Member of Congress

Sanford D. Bishop, Jr.

Sanford D. Bishop, Jr.
Member of Congress

Henry C. 'Hank' Johnson, Jr.

Henry C. "Hank" Johnson, Jr.
Member of Congress

John Lewis

John Lewis
Member of Congress

Tom Price, M.D.

Tom Price, M.D.
Member of Congress

Rob Woodall

Rob Woodall
Member of Congress

Austin Scott

Austin Scott
Member of Congress

Doug Collins

Doug Collins
Member of Congress

Jody Hice

Jody Hice
Member of Congress

Barry L. Undermilk

Barry L. Undermilk
Member of Congress

Rick W. Allen

Rick W. Allen
Member of Congress

David Scott

David Scott
Member of Congress

Tom Graves

Tom Graves
Member of Congress

Congress of the United States
Washington, DC 20515

November 05, 2015

Mr. James Macrae
Acting Administrator
Health Resources and
Services Administration
5600 Fishers Lane
Rockville, MD 20857

Cmdr. Krista Pedley
Director, Office of Pharmacy Affairs
Health Resources and
Services Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Acting Administrator Macrae and Commander Pedley:

We write to ask that any revised guidelines to the 340B Program ensure access to Hemophilia treatment center services for the more than 1,400 Georgia patients currently relying on them. We are concerned that new requirements may unintentionally place medically vulnerable patients at risk by jeopardizing continued and meaningful participation in the 340B Program.


We have heard from Hemophilia of Georgia (HoG), one of the original hemophilia organizations to be designated as a covered entity under the 340B Program in 1992 with an innovative model of care that is nationally recognized for its excellence. HoG is a nonprofit organization based in Atlanta which provides services and support for Georgians who have hemophilia, von Willebrand disease, and other inherited bleeding disorders. Due to the high costs of treatment and complications associated with hemophilia and related inherited bleeding disorders, the bleeding disorders community is medically vulnerable.

HoG operates a nonprofit 340B accredited pharmacy that has provided discounted clotting medications to thousands of patients with bleeding disorders across our state. The 340B pharmacy revenue has allowed HoG to give significant, ongoing financial support to all Georgia Hemophilia Treatment Centers: Emory University in Atlanta, Emory/Children's Healthcare of Atlanta, Georgia Regents University in Augusta, and Memorial Hospital in Savannah. Consistent with Congress' intent regarding the establishment of the 340B Program, these funds make it possible to stretch scarce resources to expand access to comprehensive medical, clinical and supportive services.

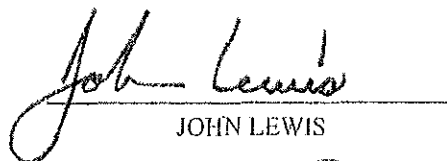
In addition, HoG's outreach nurses and social workers attend clinics and visit patients in their homes. This continuity of care from clinic to home has greatly enhanced patients' ability to manage their bleeding disorders, keeping them healthy and out of the hospital. Many of these team-based services are not ordinarily covered by insurance, and HoG does not bill its patients or their families for these services. Without the resources from the 340B Program, many of these comprehensive services would not be available.

As you work to revise guidelines for the 340B Program, we ask you to ensure, consistent with applicable law, rules, and regulations, that any changes will allow continued access to comprehensive services for 340B patients with bleeding disorders across Georgia. More than 1,400 patients, their families, and the Georgia Hemophilia Treatment Centers rely on Hemophilia of Georgia. Restricting patient access to this organization's services could place patients' health at risk and potentially increase the overall costs of their care.

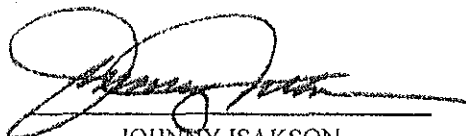
Yours truly,



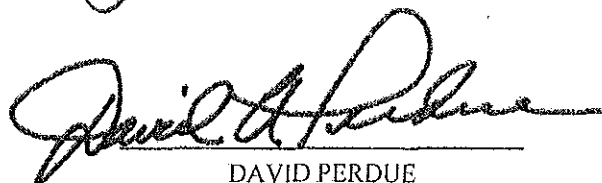
TOM PRICE, M.D.



JOHN LEWIS



JOHNNY ISAKSON



DAVID PERDUE



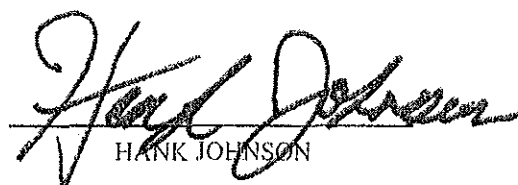
BUDDY CARTER



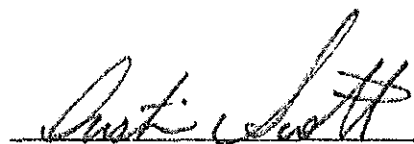
DAVID SCOTT



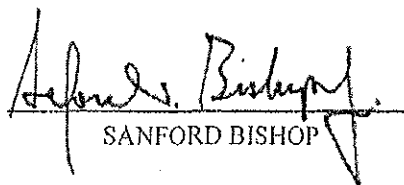
RICK ALLEN



HANK JOHNSON



AUSTIN SCOTT



SANFORD BISHOP



LYNN WESTMORELAND



JODY HICE



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services
Administration

Rockville MD 20857

December 9, 2015

The Honorable Tom Price, M.D.
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Price:

Thank you for your letter regarding the Health Resources and Services Administration's (HRSA) 340B Drug Pricing Program (340B Program) and the importance of continued access to comprehensive services for patients in Georgia with bleeding disorders. We share your views that Hemophilia of Georgia provides valuable comprehensive services to patients in Georgia. In addition to participating in the 340B Program, Hemophilia of Georgia has been a HRSA grantee for many years and our staff has met with them on multiple occasions.

HRSA issued the proposed 340B Omnibus Guidance to address key policy issues raised by various stakeholders committed to ensuring the integrity of the 340B Program and to assist covered entities and manufacturers in their ability to satisfy 340B Program requirements and expectations. The proposed 340B Omnibus Guidance is intended to provide increased clarity in the marketplace for all 340B Program stakeholders and strengthens HRSA's ability to administer the 340B Program effectively. The proposed 340B Omnibus Guidance was open for review and public comment in the *Federal Register* (80 FR 52300 (August 28, 2015)) with a 60-day comment period, which closed on October 27, 2015. HRSA is now analyzing the comments received in an effort to develop the final 340B Omnibus Guidance.

Again, thank you for your interest in the 340B Program and for bringing the concerns of the 340B Program stakeholders to my attention. Identical letters were sent to the co-signers of your letter.

Sincerely,


James Macrae
Acting Administrator

LYNN A. WESTMORELAND
3RD DISTRICT, GEORGIA

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DEPUTY WHIP

Congress of the United States
House of Representatives
Washington, DC 20515-1003

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FINANCIAL SERVICES
SUBCOMMITTEE ON FINANCIAL INSTITUTIONS
AND CONSUMER CREDIT
SUBCOMMITTEE ON HOUSING AND INSURANCE
SUBCOMMITTEE ON CAPITAL MARKETS AND
GOVERNMENT SPONSORED ENTERPRISE

HOUSE PERMANENT SELECT
COMMITTEE ON INTELLIGENCE
CHAIRMAN, SUBCOMMITTEE ON OVERSIGHT

April 14, 2014

APR 22 '14 PM 12:51

The Honorable Mary Wakefield
Administrator
U.S. Department of Health and Human Services
Health Resources and Services Administration
200 Independence Avenue, S.W.
Washington, DC 20001

Dear Administrator Wakefield,

We have recently learned that the United States Department of Health & Human Services (HSS) and the Health Resources and Services Administration (HRSA) plans to re-map the current regional structure for the allocation of liver transplants. With several high performing transplant centers in Georgia, we are concerned that the proposed redistricting will have a negative impact on our state and the region overall. In 2013, Georgia performed between 170 and 180 liver transplants. Additionally, more than 50 livers transplanted annually in the state of Georgia come from the surrounding states in Region 3. The proposed remapping would reduce the number of liver transplants performed in Georgia by 25%, reducing access to this life saving procedure for Georgians and the surrounding populations currently included in Region 3.

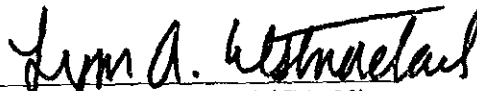
The proposed remapping would single out the state of Georgia, making it the only southern state in a region comprised of northeastern states. This proposed region will inevitably drive up costs, decrease survival rates, and waste precious resources in an already constrained sector of healthcare. The average travel time for a liver in the current structure is 3-5 hours compared to 5-8 hours in the proposed structure. Additionally, increased travel time for a liver from Georgia to New Jersey could significantly decrease the survival rate of the organ. In the event of a flight delay or cancellation, the driving time from Georgia to New Jersey far exceeds the five hour lifespan of a liver. The necessity for jet travel by remapping will increase transplantation costs by \$525,000 per 100 organ donors. Furthermore, costs for patients will inevitably increase under the proposed structure. If the organ must travel the distance in the new structure, the patient incurs greater risk of complications and therefore a longer recovery period, driving up the total cost for their stay.

The proposed remapping also disproportionately harms our most vulnerable patients. With 13.7% of Region 3 patients living below the federal poverty level and supported by Medicaid, compared to 12.3% nationally, this change will severely burden the Medicaid system.

Also, due to the higher percentage of minorities in Georgia, the Southeast, and Region 3, the proposed remapping will negatively impact their access to transplantation and thus widen the disparities of donor organ access for minorities and lower socioeconomic patients.

Because this reallocation was not developed in any accordance with Congressional involvement or oversight, we ask that you put a hold on the UNOS process, as many members of the UNOS do not agree with the expanding sharing models or with the remapping models. Patients have been through such an ordeal to even be considered for a liver transplant. Please spare them additional regulatory and administrative burdens that could place their lives at greater risk.

Sincerely,



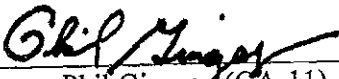
Lynn Westmoreland (GA-03)
Member of Congress



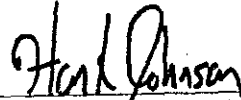
Paul Broun (GA-10)
Member of Congress



Doug Collins (GA-09)
Member of Congress



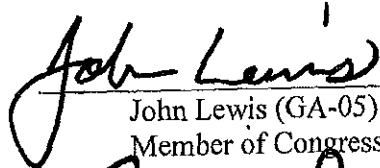
Phil Gingrey (GA-11)
Member of Congress



Hank Johnson (GA-04)
Member of Congress



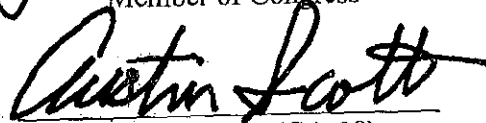
Jack Kingston (GA-01)
Member of Congress



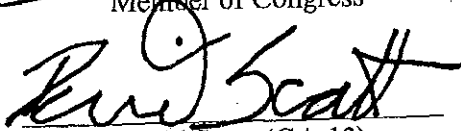
John Lewis (GA-05)
Member of Congress



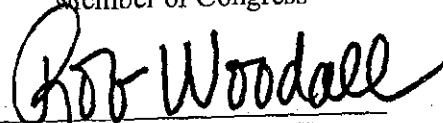
Tom Price (GA-06)
Member of Congress



Austin Scott (GA-08)
Member of Congress



David Scott (GA-13)
Member of Congress



Rob Woodall (GA-07)
Member of Congress



MAY 14 2014

The Honorable Tom Price
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your letter regarding the Organ Procurement and Transplantation Network (OPTN) liver allocation policy, and specifically, how any future change in such policy may impact transplant centers in Georgia. The Health Resources and Services Administration (HRSA) is responsible for overseeing the operation of the OPTN to ensure equitable allocation of donor organs for transplantation. The OPTN organ allocation policies are developed through a deliberative process with input from experts in the field, transplant recipients, candidates, donor family members, living donors, and with an opportunity for public comment.

As mentioned in a letter from the chair of the OPTN Liver and Intestinal Organ Committee (Liver Committee), which was sent to the OPTN liver transplant programs on April 29, 2014, (<http://optn.transplant.hrsa.gov/news/newsDetail.asp?id=1647>), the OPTN is considering revisions to the regions currently used in OPTN liver allocation policy, including the "re-mapping" of the current regional structure for allocation of livers. Once a policy proposal has been finalized, there will be opportunity for public comment as part of the established the OPTN policy development process.

The OPTN and HRSA have noted that there is significant inequity across the current OPTN regions in patient access to livers resulting in significantly longer waiting times in some regions. Through the OPTN's policy development process, the OPTN Liver Committee is working with the Scientific Registry of Transplant Recipients (SRTR), which is operated under contract by HRSA, to examine potential new districts for liver allocation that are based on empirical data and mathematical methods.

In addition, any change in the OPTN liver allocation policy must be consistent with the principles established in the National Organ Transplant Act of 1984, as amended, and the regulations governing the operation of the OPTN, which outline the goals to be achieved through the OPTN organ allocation policies. The regulations require allocation policies be based on sound medical judgment and seek to achieve the best use of donated organs, be designed to avoid the wastage of organs, avoid futile transplants, promote patient access to transplantation, promote the efficient management of organ placement, and not be based on a candidate's place of residence or listing (except to the extent necessary to satisfy other requirements), per 42 CFR § 121.8. The OPTN has explained that the goal of any proposed revision to the OPTN regional structure for purposes of liver allocation will be to increase access to livers for patients with the most medical urgency and decrease geographic disparity for such patients.

We appreciate your concerns regarding the potential impact of any change in the OPTN liver allocation on minority populations. In this work, the OPTN and SRTR are monitoring the potential impact of any future liver allocation policy changes on minority populations.

Thank you again for your interest in the national liver allocation policy. Identical letters have been sent to all other signatories.

Sincerely,

A handwritten signature in cursive script that reads "Mary Wakefield". The signature is written in black ink and is positioned above the printed name and title.

Mary K. Wakefield, Ph.D., R.N.
Administrator

TOM PRICE, M.D.
6TH DISTRICT, GEORGIA

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CANTON, GA 30114
(678) 493-6178

www.house.gov/tomprice



Congress of the United States
House of Representatives

November 16, 2010

COMMITTEE ON
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DEPUTY RANKING MEMBER
DOMESTIC AND INTERNATIONAL POLICY

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EDUCATION AND LABOR
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WORKFORCE PROTECTION
RANKING MEMBER
HEALTH, EMPLOYMENT, LABOR AND PENSIONS
RANKING MEMBER

REPUBLICAN STUDY COMMITTEE
CHAIRMAN

DEPUTY WHIP

Mr. James R. Esquea
U.S. Department of Health and Human Services
Hubert Humphrey Building, Room 416 G
200 Independence Avenue, Sw
Washington, DC 20201-0001

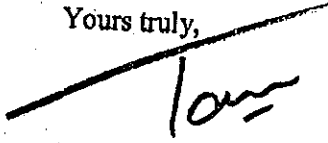
Dear Mr. Esquea:

My constituent, Ms. Kimberly Webster, has contacted me regarding a problem she is having. Please find enclosed a copy of her correspondence.

Please verify the status of this situation and provide me with any information that I may use to properly assist my constituent. Please forward all correspondence to the attention of Tina McIntosh in my Marietta District Office at 3730 Roswell Rd., Suite 50, Marietta, GA 30062. You may also contact her by phone at 770-565-4839, by facsimile at 770-565-7570, or by email to tina.mcintosh2@mail.house.gov.

Thank you in advance for your time and assistance in this matter. I look forward to hearing from you soon.

Yours truly,


Tom Price, M.D.
Member of Congress

TP/tm

Congressman Price, my name is Kimberly Webster and you are my elected representative.

I have written you in the past, as recently as last month and I appreciate your reply and the assistance you provided me. Today I am writing to express to you my concerns regarding the U.S Department of Health and Services' National Health Service Corp program and the type of health care professionals that are eligible. While this program is a great resource and an amazing way to get more people involved in the health care profession by allowing loan repayment and scholarships for those who dedicate to a minimum service commitment to expand access of health care services and improve the health of people who live in urban and rural areas where health care is scarce, it does not allow for those of use who are dedicating our lives to Nutrition as it relates to overall wellness in these same communities and are also willing to dedicate ourselves to the same kind of minimum service commitment. Nutrition or lack of nutritional education resources happens to be one of the major reasons why our society is in need of extensive health care; it is a trickle down effect that is directly related. We, as a country, are willing to create and educate more people to become doctors, nurses, psychiatrists, dentists, etc but we are not willing to invest in and educate more individuals to focus on our human nutrition and its ability to help conquer diabetes, high cholesterol that leads to heart disease and obesity to name a few.

I would like to know exactly what it would take to include Dietitians and Clinical Nutritionists as a part of this wonderful NHSC program. Besides this correspondence to you, where do I start and to whom else do I reach out to? I am currently enrolling in higher education for a Master in Human Nutrition to become Clinical Nutritionist, something that I am deeply passionate about. My goal is to work in the community to educate our children from the ground up about the importance of eating and being mindful of where our food comes from. My hope is to help eradicate and rehabilitate childhood obesity so that our future does not fall victim to the effects of what the lack of this knowledge will ultimately do to our society in an effort to leave our country in the hands of healthy individuals for generations to come that at minimum have the ability to make better nutritional decisions for themselves. It is imperative that the NHSC program allows for people like me so that others are also influenced to want to be in the Nutrition industry.

Thank you in advance for your time and your help. I look forward to hearing from you.

Kimberly Webster



(b) (6)





DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services
Administration

Bureau of Clinician Recruitment and Service

Rockville MD 20857

DEC 14 2010

The Honorable Tom Price
Member, U.S. House of Representatives
3730 Roswell Road, Suite 50
Marietta, Georgia 30062

Dear Representative Price:

Thank you for your letter on behalf of Ms. Kimberly Webster regarding the disciplines eligible for inclusion in the National Health Service Corps (NHSC).

The NHSC was established to recruit and retain primary care physicians, nurse practitioners, certified nurse midwives, physician assistants, dentists, dental hygienists, behavioral and mental health providers to provide primary health care services to underserved populations in health professional shortage areas.

The Public Health Service Act, which authorized the NHSC, defines "primary health services" as "health services regarding family medicine, internal medicine, pediatrics, obstetrics and gynecology, dentistry, or mental health, that are provided by physicians or other health professionals" (42 US Code Sec. 254d(a)(3)(D)). It further defines the term "behavioral and mental health professionals" to include "health service psychologists, licensed clinical social workers, licensed professional counselors, marriage and family therapists, psychiatric nurse specialists and psychiatrists" (42 US Code Sec. 254d(a)(3)(E)(i)).

To date, the interpretation of the statute has been that nutritionists do not qualify as providing "primary health services." That being said, there is currently a review of NHSC policies and processes underway. More specifically, this review includes a study on the eligible disciplines currently participating in the NHSC and the possible inclusion of additional disciplines, such as dietitians and nutritionists. In addition, the NHSC has conducted a survey of Community Health Centers and other NHSC-approved sites to determine the demand for additional disciplines in the NHSC. Then, the NHSC would have to review the Public Health Service Act to determine whether it has the authority to include additional disciplines. Any updates to the eligible disciplines will be announced through program guidance.

Please be assured that we will continue to review the policies and processes of the NHSC to ensure that primary health care needs are being met.

Sincerely,

A handwritten signature in cursive script that reads "Rebecca H. Spitzgo".

Rebecca H. Spitzgo
Associate Administrator

TOM PRICE, M.D.
8TH DISTRICT, GEORGIA

WASHINGTON, DC OFFICE:
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Congress of the United States
House of Representatives

COMMITTEE ON
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OVERSIGHT
FINANCIAL INSTITUTIONS
DOMESTIC AND INTERNATIONAL POLICY

COMMITTEE ON
EDUCATION AND THE WORKFORCE
SUBCOMMITTEES:
WORKFORCE PROTECTION
21ST CENTURY COMPETITIVENESS

ASSISTANT DEPUTY WHIP

November 21, 2005

Dr. Elizabeth Duke
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Room 14-05
Rockville, MD 20857-0002

Dear Dr. Duke:

Please accept this letter in support for the Grady Health System Competing Continuation application for HRSA Nurse Education, Practice and Retention (HRSA-06-038; CFDA 93.359) Grant Funding under title VII of the U.S. Public Health Service (PHS) Act. Your re-approval of this grant will enable Grady Hospital to continue to improve public healthcare in the state of Georgia.

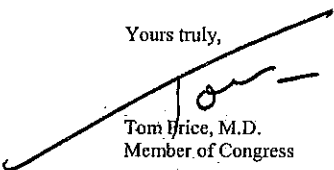
The continuation of this grant will allow Grady Health Systems to uphold their dedication to providing assistance in recruitment, education and retention of potential nurses as well as developing and implementing internship and residency training programs for recent graduates.

Grady Hospital is the largest public hospital in Georgia and is the only Level One Trauma Center serving north Georgia. Grady is home to Georgia's only poison center, one of the nation's largest burn units, one of the nation's top infectious disease programs and is a certified primary stroke center.

Grady Health Systems is committed to the health needs of those most vulnerable as well as providing excellent opportunities for nurses. As the grant would continue to assist Grady Health System eliminate the critical nursing shortage that exists, I fully support their grant application to implement a nursing internship program and residency program.

If you have any questions, please contact Debbie DeLong in my office at 770-565-4990.

Yours truly,


Tom Price, M.D.
Member of Congress

TP/dd

CC: CDR Daniel Reed, MPH


PRINTED ON RECYCLED PAPER



SEP 16 2005

Rockville, Maryland 20857

The Honorable Tom Price
Member, U.S. House of Representatives
Sixth Congressional District of Georgia
3730 Roswell Road, Suite 50
Marietta, Georgia 30062

Dear Mr. Price:

Thank you for your fax of August 2 to the Department of Health and Human Services, Congressional Liaison Office on behalf of your constituent, Mr. Max Staples. It was referred to the Health Resources and Services Administration (HRSA) for reply.

In his note to you, Mr. Staples asks about obtaining information on HRSA grant awards, including a list of HRSA grant recipients and their grant applications. Copies of awarded grant applications must be requested through the HRSA Freedom of Information Office (FOIA). I have enclosed guidance on how Mr. Staples can obtain these files through a FOIA request. In addition, compilations of HRSA grant awards from fiscal years 1999-2005 are stored in the HRSA Geospatial Data Warehouse. The link to that Web site is: <http://www.datawarehouse.hrsa.gov/grants.htm>. Under the heading entitled "Key Program Areas" your constituent can select "Reporting Tools," the link which will take him to "HRSA Grant Programs." Information on HRSA grantees is located there.

I hope this information is helpful to your constituent.

Sincerely,

Nancy J. McGinness
Associate Administrator
Office of Federal Assistance Management

Enclosure

A Guide for Requesting Information and Records from HRSA

HRSA's documents include those produced for public dissemination and others that result from day-to-day agency operations. This guide will assist you in obtaining these documents either directly or through a Freedom of Information Act (FOIA) request.

Obtaining Public Information

Public information documents--such as press releases, consumer publications, speeches, and congressional testimony--are available from HRSA without having to file a FOIA request. Many of these documents are available on HRSA's Internet site (<http://www.hrsa.gov>). We encourage you to browse the site for documents which might be of interest. You can also search for major information systems maintained by HRSA by using the Department of Health and Human Services (DHHS) Government Information Locator Service (GILS) site. This information may be useful in narrowing a request.

For additional information, please contact the Office of Communications, Attn: Freedom of Information, Health Resources and Services Administration, 5600 Fishers Lane, Rm. 14-15, Rockville, MD 20857; telephone (301) 443-2865, fax (301) 480-5285.

Obtaining Information Through FOIA

Any individual may submit a FOIA request to HRSA by mail, fax, e-mail or in person. The request must be in writing. Telephone requests cannot be processed.

Address your fax, e-mail, or written request to:

*Health Resources and Services Administration
Office of Communications
Freedom of Information
5600 Fishers Lane, Rm. 14-15
Rockville, Maryland 20857
fax: (301) 480-5285
e-mail: foia@hrsa.gov*

In your request, identify the record(s) that you want. If you do not know the exact title, describe the record as specifically as possible. The more details that you can provide, such as author, title, date, subject matter, and location, the better. A vague or incomplete description could delay our response or prevent us from finding the records you want. We may ask you to clarify your request if necessary. FOIA staff will log your request, assign a tracking number to it and send you a letter acknowledging receipt of your request. This number is important to you because it will enable us to check the status of your request.

FOIA Fees

FOIA authorizes us to assess the following three levels of fees: search fees, review fees and photocopying fees. The fees that we assess for a given request, however, are based upon the category of FOIA requester.

Fee Categories

For fee purposes, the FOIA requires that requesters be placed in one of the following three categories: (1) commercial use requesters; (2) educational and scientific institutions and news media, and (3) all others. In line with FOIA, we charge commercial use requesters the costs of search, review and duplication associated with processing requests. We charge scientific, educational and news media requesters the cost of duplication only, except that we provide the first 100 pages free of charge. We charge all other requesters the costs of search and duplication, except that the first two hours of search and the first 100 pages of duplications are free of charge. You will be billed only if the total processing charges are \$25 or more.

We assume that you are willing to pay the fees we charge for processing your request. In your letter of request, you may specify the fee category in which you feel your request falls. You also may state the maximum amount of fees that you are willing to pay.

Fee Waivers

The FOIA permits agencies to waive fees if disclosure of the record(s) is in the public interest because it: (a) is likely to contribute significantly to public understanding of the operations or activities of the government and (b) is not primarily in the commercial interest of the requester.

If you believe that your request meets both of the above tests, you can request a waiver or reduction of fees when you make your FOIA request. Be sure to fully document and justify your waiver request.

How We Process Your Request

We try to handle your request within 20 working days from the date we receive it. Sometimes it may take longer depending on the kind of record(s) you request and the number of requests ahead of yours. FOIA requests are processed on a "first in" "first out" basis. The guidelines we follow in processing your FOIA request are detailed in DHHS' implementing Public Information Regulations, 45 CFR Part 5.

Expedited Process

We provide expedited processing when disclosure of the records is necessary because of a compelling need. This is the case when the requester: (1) demonstrates an imminent threat to life or physical safety; and (2) is a member of the media and demonstrates urgency to inform the public concerning actual or alleged government activity. We also will expedite your request if you show that the requested records are needed to meet a deadline in litigation or a deadline imposed by a governmental agency for commenting on a proposed regulation.

If you would like your request expedited, please explain your reasons in your FOIA request.

Denials and Appeals

If a record is determined to be exempt from release under the FOIA, in whole or in part, we will provide written notification to you of this decision. We will explain our reason(s) for withholding the record/information and describe how you may file an appeal. Any administrative appeal decision that upholds a denial will inform you of the basis for the denial and of your right to judicial review in Federal courts.

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U.S. Representative Tom Price, M.D.

Sixth Congressional District of Georgia

3730 Roswell Road, Suite 50

Marietta, GA 30062

Phone: (770) 565-4990

Fax: (770) 565-7570

DATE: 2 Aug '05

TO: HHS Congressional FAX #: 202-690-7380

FROM: Jared Thomas _____ Debbie DeLong: _____
Jeff Hamling _____ Tina McIntosh X

RE: Thank you for your help.

Please reply to the above
address or fax.

Jane

There are 2 pages to this fax.

Confidential Notice: This facsimile, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender immediately and destroy all copies of the original message.

From: "mstaples@secureworks.com" <mstaples@secureworks.com>
Date: 7/20/2005 12:12:07 PM
To: ga06ima@mail.house.gov
Subject: Message for Tom Price - Technology

<APP>CUSTOM
<PREFIX>Mr.</PREFIX>
<FIRST>Max</FIRST>
<MIDDLE></MIDDLE>
<LAST>Staples</LAST>
<SUFFIX>III</SUFFIX>
<ADDR1>765 Edgewater Trail</ADDR1>
<CITY>Atlanta</CITY>
<STATE>GA</STATE>
<ZIP>30328</ZIP>
<EMAIL>mstaples@secureworks.com</EMAIL>
<MSG>Hi,

I'm hoping that someone in your office can help me. I'm trying to find out how I can track HRSA (www.hrsa.gov) grant awards.

My company, Secureworks (www.secureworks.com), is an Atlanta-based computer security firm focusing on a few select industries, including healthcare. Being able to see a list of grant recipients would help us tremendously in targeting our sales and marketing efforts.

I'm hoping that grant recipients (and their grant applications) are a matter of public record, but I can't figure out how to access that information.

Thanks in advance for your assistance,
Max Staples</MSG>
</APP>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services
Administration

Rockville MD 20857

DEC 14 2005

The Honorable Tom Price, M.D.
House of Representatives
Washington, D.C. 20515

Dear Dr. Price:

Thank you for your letter in support of the application submitted by Grady Health System for the Nurse Education, Practice and Retention (NEPR) grant program.

An Objective Review Committee will meet in early 2006 to evaluate applications submitted for the NEPR program. Please be assured that the application will receive full and equitable consideration. Funding decisions are then expected to be completed and awards made depending upon the availability of fiscal year 2006 funds. If the application is funded, the Department's Congressional Liaison Office will notify you.

Please call me if you have any further thoughts or questions.

Sincerely,

A handwritten signature in cursive script that reads "Elizabeth M. Duke".

Elizabeth M. Duke
Administrator

Atkinson, Leslie (HRSA)

From: DiBlasio, Carla <Carla.DiBlasio@mail.house.gov>
Sent: Wednesday, August 24, 2016 6:41 PM
To: Sealy, Camille (HRSA)
Cc: Hacking, Rose (HHS/ASL); Atkinson, Leslie (HRSA)
Subject: RE: 340B Concerns

Thanks, Camille.

We appreciate your consideration.

Carla DiBlasio
Senior Policy Advisor/Legislative Counsel
Congressman Tom Price, M.D. (GA-06)
100 Cannon House Office Building
Washington, DC 20515 | 202.225.4501

From: Sealy, Camille (HRSA) [mailto:CSealy@hrsa.gov]
Sent: Wednesday, August 24, 2016 12:45 PM
To: DiBlasio, Carla
Cc: Hacking, Rose (HHS/ASL); Atkinson, Leslie (HRSA)
Subject: RE: 340B Concerns

Hi Carla,
I hope this message finds you well.

Thanks for your inquiry regarding HRSA's 340B Drug Pricing Program (340B Program) and the status of the proposed 340B Omnibus Guidance. As you know, the proposed guidance was open for review and public comment in the *Federal Register* (80 FR 52300 (August 28, 2015)) with a 60-day comment period, which closed on October 27, 2015. HRSA is currently analyzing the comments received to develop the final 340B Omnibus Guidance. We are targeting December 2016 for publication of the final guidance. We understand the importance of the 340B Program to you and your constituents and appreciate you reaching out on this matter.

If you should have additional questions, please do not hesitate to reach out.

Sincerely,
Camille

From: DiBlasio, Carla [mailto:Carla.DiBlasio@mail.house.gov]
Sent: Wednesday, August 24, 2016 11:56 AM
To: Sealy, Camille (HRSA)
Subject: 340B Concerns

Camille,

I hope this email finds you well. I handle healthcare for Congressman Tom Price. Emory University recently presented us with a list of concerns regarding 340B. We greatly appreciate your attention to their concerns as described in their comments below. Any feedback you can provide us on any of these concerns would also be greatly appreciated.

Emory University Hospital Midtown (EUHM), a 511-bed academic community hospital in the heart of midtown Atlanta, is a strong supporter of the 340B program and its impact on our patients. As a DSH facility in a large urban area, it is our role to ensure access to world-class care to our community's most vulnerable patients. Access to 340B pricing allows us to fulfill this mission and improve the overall health of our city.

EUHM takes compliance with HRSA guidance extremely seriously. We are committed to running a highly compliant program and we are excited to see additional clarifying statements provided in the omnibus proposal. In reviewing the proposed language, we found some content to be of concern and we thank you for the opportunity to provide feedback. Please find a summary of our comments below.

1. Hospital Relationships with Their Providers

- a. We do not understand what HRSA intends with the requirement that we have employment or independent contractor relationships with our providers such that we may bill for their services. Currently EUHM has a mix of employed physicians, community / private practice physicians who are active medical staff at EUHM, and GME residents and fellows. We review our list of eligible providers daily to ensure that all providers are active medical staff at EUHM.
 - a. We request that HRSA remove this requirement, as the remaining requirements in this area already limit 340B use to services and prescriptions that are written in the hospital or one of its registered locations, thereby ensuring hospital responsibility for the services
 - b. If HRSA intends to maintain this requirement, then we request that HRSA revise and republish it for comment. As written, we do not believe we have a meaningful opportunity to comment because the language used is too vague
 - c. If HRSA intends for this provision to impose new standards for the health industry regarding provider contracting (e.g., outside of what is currently required by health programs and the Joint Commission), HRSA needs to more clearly articulate what would be required
- b. Issues related to who is an "independent contractor" of the hospital:
 - i. The guidance would require that for a provider to be able to write a prescription or order for a 340B drug, the provider must be an employee or "independent contractor" of the hospital.
 1. While many of our providers are employed through Emory University, our community / private practice physicians are neither employees nor do they have a contract with the facility
 2. All EUHM providers undergo a rigorous credentialing process prior to becoming "active medical staff"
 - ii. Using an "independent contractor" standard is not appropriate for guidelines, as the legal rules in this area are not subject to a national standard and vary significantly by state and even within states.
- c. Issues related to what HRSA means by "may bill for services on behalf of the provider":
 - i. The language stating that hospitals must have arrangements such that they "may bill for services on behalf of the provider" is even more unclear. Does this refer to services that hospitals bill in connection to services furnished by a provider (e.g., the facility fee)? Or does it refer to billing for the professional services furnished by our providers?

2. Orders for Infusion

- a. EUHM, as the infusion provider for the nationally recognized Winship Cancer Institute, will reach in excess of 100,000 infusion visits in calendar year 2015. Access to 340B pricing for our infusion center allows EUHM to provide millions of dollars in charity care directly associated with the treatment of hematologic and oncologic conditions, funds direct access to these sites through transportation subsidies, improves overall patient experience through the funding of dietitians, clinical pharmacy specialists, nursing navigators, midlevel clinical providers and clinical nurse educators, and funds a robust patient assistance program for oral therapies and a

co-pay assistance program for infusion related therapy. These programs simply could not exist without access to 340B pricing.

- b. The proposed guidance would only allow 340B for infusion orders if they were written as a result of services provided in the hospital or a registered child site.
- c. EUHM owns many of the hematology / oncology clinics that refer patients to our infusion centers but we also accept patients who have been seen at non-EUHM clinics for their medical care.
- d. Individuals receiving infusion at the hospital are unquestionably hospital patients, even if the order is written in a location outside the hospital. The individuals are registered as hospital patients and the hospital is responsible for administering the infusion and is required to provide health care services in conjunction with the drug's administration.
- e. No other government program or other health care payer requires infusion orders to be written at the hospital as a condition of payment. HRSA is proposing a 340B-specific requirement for infusion orders that does not exist anywhere in health care policy.
- f. Administration of infusion drugs are highly complex services, requiring skill and direct attention, and may only be performed by trained health care professionals. Failure to administer infusion drugs appropriately can result in severe consequences for the patient, for which the hospital is responsible.
- g. The concerns about this proposal exist even if GPO pricing were permitted for these drugs.
- h. Imposing this unique 340B standard would require hospitals to develop new tracking systems to distinguish their outpatients for whom an order was written on the premises of the hospital and those for whom the order was written outside the hospital. Since the individuals receive the same hospital outpatient services in both cases, this tracking is not currently necessary and would impose a new burden on safety-net hospitals and is one that may not even be feasible.

3. Discharge Prescriptions

- a. The proposed guidance would prohibit hospitals from using 340B pricing for drugs that are billed as outpatient drugs if the script/order was written in connection to a discharge from an inpatient stay.
- b. Using 340B for discharge prescriptions is a longstanding practice that allows 340B hospitals to reduce readmissions for their patients, is easy to administer and audit, and is consistent with the purpose of the 340B program.
- c. As a 340B hospital, we discount the cost of medications provided upon discharge for our low income patients to help ensure that patients can get the drugs they need. Over the last 3 fiscal years, EUHM has provided approximately \$300,000 annually in uncompensated discharge medication to uninsured and low income patients to transition the patient to the next level of care. Without access to 340B pricing for discharge prescriptions, we will not be able to support the same level of support.
- d. Eligibility for 340B pricing should be applied to all drugs furnished in connection to services received at the hospital, for registered hospital patients, and that are billed on an outpatient basis. This is an easy bright line rule for hospitals to follow and for HRSA to audit. EUHM currently audits 100% of all discharge prescriptions using 340B drugs to ensure that they meet the requirements as outlined in the current guidance.
 - 1. Tracking discharge prescriptions that tie to an inpatient service so they could be excluded from 340B would be operationally challenging and burdensome because hospitals generally do not track in their retail pharmacies whether a prescription resulted from an outpatient encounter. Compliance with the proposed change would require significant modifications to hospital systems.
- e. 340B pricing is available under the 340B statute for "covered outpatient drugs." There is no requirement under the 340B statute that covered outpatient drugs that are billed as outpatient drugs must also pertain directly to an outpatient service. Indeed, many hospitals are able to participate in the 340B program only by demonstrating that they provide *inpatient* services to a disproportionate number of low income patients. It would be inconsistent with the statute to deny 340B pricing for outpatient prescriptions needed by those low income patients upon discharge.

4. Outpatient Services That Are Not Billed As Outpatient

- a. The proposed guidance would prohibit use of 340B for drugs given to hospital outpatients if the patient's insurer requires that the outpatient service resulting in the script/order being written be included in a bill for inpatient services.
- b. This new proposed policy would change HRSA's longstanding rules in this area and is inconsistent with the purpose of the 340B program. The purpose of the 340B program, in contrast, is to allow providers that treat a significant share of low income individuals to stretch their resources and provide more services to more patients. The purpose of insurer billing rules that include outpatient services with inpatient is to save money for insurers.
- c. Insurance company billing rules do not change the underlying nature of the service or drug provided. A drug given to a registered hospital outpatient is still an outpatient drug regardless of how the insurer requires that it be billed or paid.
- d. Hospitals should be able to use 340B for drugs administered in outpatient settings, regardless of whether the drug is billed as part of an inpatient stay, if the patient was an outpatient at the time the drug was administered or if the drug itself was billed on an outpatient basis.
- e. This proposed policy would impose significant operational challenges:
 - i. EUHM currently utilizes a commercially available accumulation software that tracks inpatient and outpatient dispenses at the time of dispensation (consistent with the current guidance for both 340b eligibility and GPO exclusion). Determination of inpatient or outpatient status is made at the point of dispensation, based on the providers order for level of care. Our commercially available accumulation software would not longer function as designed.
 - ii. Rules about inpatient and outpatient status may differ depending on the payer.
 - iii. Subsequent payer determinations make tracking more challenging and we are frequently finding that we do not finality to patient status for weeks after the initial bill has been submitted to the payor.
 - iv. Unfortunately, payer determinations are more and more frequently not aligning with the provider's determination about the appropriate patient status or level of care.

5. Bundled Medicaid Drugs

- a. 340B covered entities should be able to use 340B for all Medicaid drugs regardless of whether the drug is bundled into payment made for other services.
- b. The 340B program allows certain hospitals to participate only if the hospitals can demonstrate that they provide a disproportionate amount of care to Medicaid and low-income Medicare patients. It would be inconsistent with the purpose of the program to disallow 340B pricing for drugs dispensed to that population.

6. GPO Prohibition - EUHM supports the three exceptions to the GPO prohibition included in the proposed guidance and requests that HRSA clarify the exceptions to allow for additional flexibility.

a. Proposed New Exceptions:

- i. **340B not available:** HRSA should not require hospitals subject to the GPO prohibition to use WAC pricing when 340B pricing is not available, such as when a:
 - 1. Drug is in shortage
 - 2. Manufacturer is refusing to offer the 340B price
 - 3. Manufacturer is not participating in 340B
- ii. **340B not permitted:** HRSA should not require hospitals subject to the GPO prohibition to use WAC pricing when 340B use is not permitted, such as when a hospital:
 - 1. Is treating an outpatient who is not eligible to receive a 340B drug (e.g., walk-in patient, ineligible employee)
 - 2. Carves-out and must provide non-340B drugs to Medicaid patients
 - 3. Is unable to track a drug appropriately to justify 340B use, such as for intravenous saline solutions, contrast agents, anesthesia gases, and other similar products.
- iii. HRSA has stated that a purpose behind its GPO prohibition policy is to prevent hospitals from buying covered outpatient drugs through 340B and GPO (i.e., to prevent "cherry picking."). In these situations, when the

340B price cannot be used, there is no danger of cherry picking. HRSA should therefore allow hospitals to use a GPO in these instances.

- b. **HRSA should allow hospitals subject to the GPO prohibition to use inventory replenishment systems based on initial GPO purchase and should not require initial purchases to be made through non-340B, non-GPO accounts (i.e. WAC).**
 - i. HRSA should clarify whether HRSA's February 7, 2013 Policy Release on the Statutory Prohibition on Group Purchasing Organization Participation still applies. In particular, does HRSA still intend to impose the requirement that hospitals subject to the GPO prohibition using virtual replenishment systems "should purchase using a non-GPO account and only replenish with 340B drugs once 340B patient eligibility is confirmed and can be documented through auditable records"? This policy release made clear that hospitals using replenishment models may not first purchase through a GPO and then replenish accordingly.
 - ii. HRSA should allow inventory replenishment systems that make initial purchases at GPO pricing, rather than using non-340B, non-GPO pricing (i.e., WAC).
 - iii. Inventory replenishment is based on the theory that the repurchased drug takes the place of the drug administered or dispensed to the patient. If a GPO drug purchase is "cured" through a subsequent 340B purchase, there is no harm to manufacturers.
 - iv. There are some cases when a hospital is not able to cure a GPO purchase through a 340B replenishment, such as when a drug is in shortage and the drug is not available at 340B for repurchasing or when the package size necessary to make a replacement order is never reached. In these situations, the hospital can cure the GPO use by replenishing at WAC, or some other non-340B, non-GPO price.
 - v. Hospitals should be able to use GPO-based replenishment systems because requiring WAC-based inventory management systems increases hospital costs, inconsistent with the purpose of the 340B program.

7. Self-Disclosure - Notification to HRSA should only be required for material changes in eligibility and material breaches of program requirements

- a. Current HRSA policy requires that covered entities report material noncompliance to HRSA. The proposed guidance suggests that all such instances must be reported, even if they are not material.
 - a. At current, EUHM has a robust and active 340B Governance Committee that reviews monthly audits of compliance. The committee is charged with identifying any corrective actions and determining materiality.
- i. The annual recertification process would require notification of "any 340B Program requirement, subject to HHS audit," while other sections would require the reporting of "all corrective actions" relating to diversion and discount discounts.
- b. HRSA should limit all disclosures to those that rise to level of being "material." Notifying HRSA of all program violations, no matter how minor, would be too burdensome for both HRSA and providers, and not provide significant program integrity value.

8. Child Site Eligibility

- a. HRSA should permit hospitals to certify that all clinics in an offsite building are 340B-eligible instead of requiring individual registration of each office.
- b. For hospitals that operate in multiple buildings, HRSA should allow a hospital to register one of its hospital buildings as the parent site and register the other buildings as child sites, so long as the hospital could attest that every outpatient clinic/department in the offsite buildings was reimbursable on the hospital's cost report. Although these offsite hospital buildings may also include inpatient areas that are not 340B-eligible, that should not preclude a hospital from registering the offsite buildings as child sites. HRSA does not require parent hospitals to register 340B-eligible outpatient areas inside the four walls of the parent site, even though parent sites generally include ineligible inpatient areas. The same policy should apply to offsite hospital buildings.
- c. Allowing these certifications would continue to ensure transparency in the registration process and provide manufacturers and other stakeholders with the information necessary to confirm covered entity compliance while making the process simpler for hospitals

- d. **HRSA should allow hospitals to register outpatient facilities without waiting for the facility to file its cost report**
 - i. The proposed guidance includes HRSA's current policy on outpatient facilities, which requires a hospital registering an outpatient facility as a child site to show that the facility's costs appear on a reimbursable line of the hospital's most-recently filed Medicare Cost Report.
 - ii. Relying only on the most-recently filed cost report can cause significant delays to registering child sites. If a hospital opens a new clinic just after the hospital filed its cost report, the hospital must wait another 17 months before filing a new cost report that includes the costs of the new clinic on a reimbursable line and then may potentially have to wait another 6 months before the hospital can register the clinic and have the clinic appear on the OPA database. Meanwhile, Medicare will not require the hospital to wait until it files a new cost report for the clinic to bill for services as part of the hospital.
 - iii. HRSA should accept alternative documentation to show that the clinic is an integral part of the hospital while the hospital waits to file a new cost report. This could include:
 - 1. Medicare 855A enrollment form
 - 2. A certification submitted to HRSA that: (1) the clinic will be listed on a reimbursable line of the cost report when the cost report is filed, (2) the hospital is currently billing for outpatient services at the clinic, and (3) the hospital agrees to repay manufacturers for 340B purchases made for the clinic if the clinic ends up not being billed on a reimbursable line of the cost report once it is filed.

9. Contract Pharmacy

- a. **HRSA should not expect covered entities to conduct an annual independent audit and quarterly reviews of each contract pharmacy location.**
 - i. A covered entity should be able to conduct a single annual independent audit or quarterly review for each contract it has with a contract pharmacy provider, rather than at each site. Typically all of the sites subject to a single agreement use the same processes and software, which is usually maintained at a central location. Requiring covered entities to audit each and every site is an unnecessary drain on resources that provides no added assurances of compliance.
 - ii. At current, EUHM conducts monthly audits of contract pharmacy transactions and an annual independent program audit is completed.
- b. **HRSA should not require contract pharmacy agreements to list all child sites that plan to use the contract pharmacy.**
 - i. This requirement would be unnecessarily burdensome.
 - 1. A covered entity would have to amend the contract pharmacy agreement whenever it adds or removes a child site.
 - 2. Nearly all existing contract pharmacy agreements would have to be amended.
 - 3. Very few contract pharmacies serve only a subset of child sites.
 - ii. The requirement would not provide additional transparency concerning a covered entity's use of its contract pharmacy, as an entity does not submit a copy of its contract pharmacy agreement to HRSA when registering a contract pharmacy.

10. Audits

- a. HRSA should make the following clarifications to the HRSA audit process of covered entities.
 - i. HRSA should publish its 340B audit protocol.
 - ii. Covered entities should have at least 30 days to respond to a pre-audit data request given the large quantity of data required for submission.
 - iii. HRSA should reinstitute the process of issuing a preliminary audit report. HRSA should communicate preliminary audit findings to covered entities and facilitate an informal dialogue among the auditor, HRSA, and the covered entity so that the covered entity can ask questions about the finding and obtain more detailed information regarding the nature of any adverse findings.
 - iv. Covered entities should have at least 90 days to respond to a final audit report.

- v. HRSA should commit to creating a mechanism to receive protected health information (PHI) in written disagreements.
- vi. When a final audit report would result in program termination, the covered entity should be able to request an in-person hearing.
- vii. HRSA should develop an independent administrative review process between the final audit report and possible judicial action, similar to the administrative law judge (ALJ) process for Medicare audits.
- viii. If HRSA does not adopt an intermediate review process, HRSA should make clear that the final audit report is final agency action that is ripe for judicial review if the covered entity continues to disagree with HRSA's findings.
- ix. HRSA proposes to work with covered entities to specify the time frame for the submission of a corrective action plan (CAP), and we appreciate HRSA's willingness to work with covered entities. HRSA should clarify that covered entities have at least 90 calendar days to submit the CAP for HRSA's approval. Covered entities could have more than 90 days, depending on the scope of the audit findings, but never less than 90 days.
- b. **HRSA should make the following clarifications to the manufacturer audit process of covered entities.**
 - i. We are pleased to see that HRSA proposes that a manufacturer must work in good faith with a covered entity to resolve a matter before the manufacturer may submit an audit work plan to HRSA. We ask that HRSA clarify that in the event that a manufacturer contacts a covered entity to request data from the entity, but is unwilling to disclose the specific reason for the request, then the manufacturer will be in violation of the good faith negotiation requirement.
 - ii. HRSA should instruct manufacturers that communications to covered entities reflecting a good faith attempt to resolve differences should include a statement indicating that the communication is not a HRSA-sanctioned manufacturer audit.
 - iii. HRSA should allow covered entities at least 60 days to respond to manufacturer data requests.
- c. **We support HRSA's plans to audit manufacturers.**
 - i. We are pleased to see that HRSA has included in the proposed guidance procedures for HRSA to audit manufacturers.
 - ii. We are also pleased that any findings would be made public, as only one audit of a manufacturer has been conducted to date and those results have not yet been made public.
 - iii. HRSA should begin auditing manufacturers on a regular basis to ensure that manufacturers are complying with 340B program requirements so that covered entities may receive the discounts they are entitled to under the program.

11. Inventory Management

- a. HRSA should clarify that improper accumulations that are fixed prior to a replacement order being made do not constitute diversion.
 - i. The preamble states that "if a covered entity improperly accumulates or tallies 340B drug inventory, *even if it is prior to placing an order*, the covered entity has effectively sold or transferred drugs..." (emphasis added).
 - ii. HRSA should clarify that diversion could not occur in a replenishment system until an incorrectly accumulated order is actually placed. Until such time, the accumulation is merely an accounting of what the covered entity may order.

12. Manufacturer Provisions

- a. We support HSRA's recognition of the manufacturer obligation to offer the 340B price and have the following comments.
 - i. The proposed guidance states that manufacturers "subject to a PPA must offer all covered outpatient drugs at no more than the [340B] ceiling price to a covered entity listed on the public 340B database."
 - ii. We appreciate that the proposed guidance reiterates HRSA's view that the "must offer" provision is a requirement for manufacturers who have entered into a PPA, regardless of whether the PPA includes the "must offer" language.

- iii. The “must offer” provision should apply to specialty drugs that are distributed through limited distribution networks. Some manufacturers have required covered entities to purchase their 340B-priced drugs through a wholesaler’s specialty drug division instead of the hospital’s usual wholesaler. HRSA should clarify that a manufacturer must allow covered entities to buy a drug through its 340B wholesale account if it would allow the same entity to purchase the drug through a non-340B wholesale account.
- iv. HRSA should clarify that a manufacturer that offers a covered outpatient drug to any entity must also offer the same drug at 340B pricing to other entities in the same class of trade.
- v. Some hospitals have faced challenges trying to buy a drug through a contract pharmacy that participates in a limited specialty pharmacy network. The guidance does not clearly address these situations. HRSA should make clear that manufacturers must provide 340B pricing to a covered entity that has a contract pharmacy agreement with a pharmacy in the manufacturer’s specialty pharmacy network.
- b. **We support HRSA’s proposal to continue its policy of asking manufacturers to notify HRSA of limited distribution plans.**
 - i. The proposed guidance states that HRSA “may” publish the details of limited distribution plans submitted by manufacturers. HRSA should make all limited distribution plans public. It is important that hospitals have access to limited distribution plans in order to assess the impact on the hospital’s operations and to plan accordingly.
- c. **We support HRSA’s proposed requirement for manufactures to issue refunds or credits for instances of overcharging within 90 days and have the following comments.**
 - i. The guidance says that HRSA expects manufacturers to issue refunds or credits for instances of overcharging within 90 days of the determination of the manufacturer or HRSA that an overcharge occurred and that covered entities that fail to accept a refund within 90 days waive their right to repayment. The guidance also states that manufacturers must submit to HHS the price recalculation information, an explanation of why the overcharge occurred, how the refund will be calculated, and to whom refunds or credits will be issued.
 - ii. Covered entities should have 1 year to accept a refund, not 90 days.
 - 1. There have been instances when a refund offer is sent to someone without the power to accept it and it takes time to get it to the correct person. There should also be time given for entities to contest a repayment amount if they do not believe it was calculated correctly.
 - 2. We recommend a one-year period to accept a refund to make sure the repayment is properly received by the covered entity.
 - iii. We support HRSA’s expanded scope of what constitutes an overcharge, which includes errors, intentional overcharges and routine pricing adjustments. We appreciate HRSA recognizing that overcharges can occur due to miscalculation, retroactive readjustments, as well as intentional overcharging.
 - iv. We support HRSA’s interest in knowing how an overcharge occurred. HRSA should expect manufacturers to submit details of overcharging within 30 days of discovery.
 - v. We support HRSA’s proposal that manufacturers may only calculate refunds on an NDC-by-NDC basis, not based on aggregated purchases, *de minimis* amounts, or netting purchases. Refunds on an NDC-by-NDC basis are the fairest way of ensuring that entities receive the correct amount of a refund for each overcharge of a single type of drug.
- d. **We support HRSA’s proposal to conduct an annual recertification process for manufacturers.**
 - i. The proposed guidance says manufacturers should annually review and update their 340B database information as part of a recertification process.
 - ii. We support this proposed process because it will improve database accuracy and enhance program compliance. It is difficult for covered entities to communicate with manufacturers, either to report errors and make repayment or request refunds for overcharges, if manufacturer contact information in the database is not correct.

Many thanks!
Carla

Carla DiBlasio
Senior Policy Advisor/Legislative Counsel
Congressman Tom Price, M.D. (GA-06)
100 Cannon House Office Building
Washington, DC 20515 | 202.225.4501

Groves, Garrick (HRSA)

From: Evans, Kim (HRSA)
Sent: Tuesday, June 21, 2016 4:47 PM
To: 'Poole, Jennifer'; McIntosh, Tina
Cc: Goldberg, Janet (HHS/ASL); Groves, Garrick (HRSA)
Subject: RE: Congressional inquiry
Attachments: Foley Hoag LLC Barker_Thomas_EHughes_201606151608.pdf

Hi, Jennifer,

Thank you for your inquiry regarding the Patients' Compensation System (PCS) and the National Practitioner Data Bank (NPDB). As you may know, PCS and its counsel, Foley Hoag, have been in contact with HRSA over the past four years regarding PCS' interest in reforming state medical malpractice systems and, more specifically, having PCS' system adopted by the states. It is HRSA's understanding that, to date, PCS' medical malpractice reform proposal has not been adopted by any state legislatures. Attached please find the response from NPDB Director Ernia Hughes to the June 22, 2015, letter from Thomas Barker at Foley Hoag. This letter outlines HRSA's response to PCS.

Please let me know if you have further questions.

Sincerely,
Kim

Kim Y. Evans, JD, MHS, Legislative Analyst
Office of Legislation
Health Resources and Services Administration, HHS
5600 Fishers Lane, 13N30A
Rockville, Maryland 20857
Phone: 301-443-3918
E-mail: kevans@hrsa.gov
HRSA Home Page: www.hrsa.gov

Improving access to health care for the underserved

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From: Poole, Jennifer [<mailto:Jennifer.Poole@mail.house.gov>]
Sent: Wednesday, June 01, 2016 12:54 PM
To: Evans, Kim (HRSA)
Cc: McIntosh, Tina; Poole, Jennifer
Subject: Congressional inquiry

Good afternoon Ms. Evans,

Thank you for your call yesterday and agreeing to look into this matter for the Congressman. (b) (6) contacted Congressman Price seeking assistance in obtaining a response from the NPDB. On June 22, 2015 Mr. Barker sent a letter to Ms. Ernia Hughes requesting an opinion letter from the NPDB that payments made by the Patients Compensation System are not reportable to the NPDB. As of this date, Mr. (b) (6) has not received a response from Ms. Hughes to Mr. Barker's letter.

For your information, please find the attached documents:

Copy of privacy release with our office

Copy of June 22, 2105 letter from Mr. Barker to Ms. Hughes

Mr. (b) (6) objective is to seek affirmation that in accordance with the Patients Compensation System, payments from the PCS are not reportable to the NPDB. I would appreciate your providing me with any information you feel may address Mr. (b) (6) concerns. Thank you for your attention to this matter. I look forward to hearing from you.

Sincerely,

Jennifer Poole
Director of Constituent Services
Office of Congressman Tom Price, M.D.
85-C Mill Street, Suite 300
Roswell, GA 30075
770-998-0049
770-998-0050 fax

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Mary Blacker (JH-ATL)

From: Poole, Jennifer <Jennifer.Poole@mail.house.gov>
Sent: Tuesday, May 31, 2016 3:02 PM
To: Mary Blacker (JH-ATL)
Subject: Congressional inquiry for Mr. (b) (6)
Attachments: Privacy Release Form.pdf

Good afternoon Ms. Blacker,

I've been in touch with a congressional liaison at the NPDB. They've requested that Mr. (b) (6) complete a privacy release form. I've attached one for his convenience. In the section that asked for an explanation, please just write "see attached".

Thank you for your assistance.

Sincerely,

Jennifer Poole
Director of Constituent Services
Office of Congressman Tom Price, M.D.
85-C Mill Street, Suite 300
Roswell, GA 30075
770-998-0049
770-998-0050 fax

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How I Can Assist You in Dealing with a Federal Agency

Thank you for contacting my office for assistance. The provisions of the Privacy Act of 1974 require me to obtain a signed Privacy Act Release Form in order to proceed with your case. This form must be completed in its entirety before an inquiry can be made on your behalf.

Things You Should Know - Your Guide to Congressional Assistance:

- Once my office has your completed, signed privacy form, the federal agency with jurisdiction over your situation will be contacted on your behalf.
- A response should be received from the agency within 45 – 60 days. This is a standard guideline and may vary for each individual case.
- When the agency's response is received, you will receive notification from my office.
- If you have an ongoing claim, further updates will be requested from the agency on your behalf.
- According to the US House of Representatives Committee on Standards of Official Conduct and due to the separation of the legislative and judicial branches of government, members of Congress cannot intervene in matters which are involved in criminal and civil legal cases. Examples of these types are listed below:
 - Legal Issues
 - Child custody issues
 - Divorce cases
- Additionally, certain cases which involve Georgia state agencies are not under my direct jurisdictional authority to intervene as a member of the federal government. However, I will forward your concerns to the appropriate state official and request that they reply to you directly. Examples of these types of cases are:
 - State Revenue taxes
 - Child support services
 - Private Insurance claims
- While I will always do my best to assist you, please remember that federal agencies have total discretion concerning decisions on individual cases.

Also, in an effort to continually improve upon the constituent services provided by my Congressional office, I have created a survey where you can provide feedback on the services you received. Your comments will be sent directly to my District Director and kept in the strictest confidence. The survey can be found on our website at <http://tomprice.house.gov/resources/constituent-assistance-federal-agencies>

Office of Congressman Tom Price, M.D.
85-C Mill Street, Suite 300
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**FOLEY
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202 223 1200 *main*
202 785 5087 *fax*

Thomas R. Barker
202 261 7310 *direct*
202 487 9610 *direct fax*
tbarker@foleyhoag.com

June 22, 2015

Ernia P. Hughes, MBA
Director, Division of Practitioner Data Banks
Bureau of Health Professions
5600 Fishers Lane, Room 8-103
Rockville, Maryland 20857

Dear Ms. Hughes:

We received your letter dated March 19, 2015 in response to our request (dated November 6, 2014) for an opinion from the National Practitioner Data Bank (NPDB) with regard to whether or not a payment made under the Patients' Compensation System (PCS) is reportable. We appreciate your response, as well as your time and consideration, as we work toward a more fair and equitable alternative to medical malpractice litigation. We are glad to see that you believe that payments made under PCS system, to the extent that patients' applications are made verbally, are not reportable to NPDB.

As we work together with state legislatures to develop new state-driven compensation systems aimed at reducing the practice of defensive medicine, alternative models to the PCS have developed that we believe also do not require reporting. This letter serves as a formal request for an opinion from the NPDB with regard to our updated model, called PCS 2.0 model, described in detail below.

PCS 2.0 shares the same goals as the PCS 1.0 model which NPDB has already evaluated ((1) to increase patient safety; (2) to reduce the cost of defensive medicine; and (3) to give patients better access to justice), but it places increased independence between the funds going into and out of the system. In particular, under the PCS2.0 model, all providers statewide pay an administrative annual fee to fund payments for medical injuries, eliminating the role of medical malpractice insurance entirely. Instead of medical malpractice insurers making payments on behalf of physicians, an independent state-based compensation committee makes awards of compensation in accordance with an established compensation schedule and the findings of an independent medical review panel.

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As discussed in detail below, we have preliminarily advised our client that reporting to the NPDB under the PCS 2.0 system is not required. We based our opinion on the longstanding Department of Health and Human Services ("the Department") interpretation, recently reiterated in the May 20, 2014 letter, that unless there is a medical malpractice claim or judgment made against a physician, there is no reportable event. (see "Appropriate Medical Malpractice Payment Reporting to the NPDB in Light of Recent Medical Malpractice Reforms in Massachusetts and Oregon – DECSION," May 20, 2014). Under the PCS 2.0, applications for compensation do not constitute a judgment or adjudication for medical malpractice, and, therefore, are not reportable to NPDB.

In addition, because patients filing an application for compensation under the PCS 2.0 do so orally (either via a phone call or an in-person visit), consistent with guidance issued by the Department, reporting is not required under the PCS 2.0. According to the Department, "should a patient only verbally demand compensation from a provider, any resulting payment would not be reportable." Under the PCS 2.0 system, a patient that believes he or she has been injured must call a toll-free hotline in order to initiate an independent medical review of their claim. Because there is no "written claim or demand for payment" under the PCS 2.0, we believe any resulting payment under the system would not be reportable, consistent with the Department's interpretation.

We appreciate you and your staff's timely attention to this request for an opinion. While we believe our opinion is wholly consistent with past Department guidance regarding reporting to the NPDB, we are requesting a formal opinion for the purpose of clarity as our client moves forward in implementing the PCS 2.0 system with its state partners.

I. The Patients' Compensation System

The aim of the Patients' Compensation System is three-fold: (1) to increase patient safety; (2) to reduce the cost of defensive medicine; and (3) to give patients better access to justice. The PCS 2.0 is a state-driven compensation system aimed at reducing the practice of defensive medicine by replacing the current medical malpractice tort system with an administrative process akin to today's state law workers' compensation system. Under the PCS 2.0, a state will establish an autonomous governance entity to act as the exclusive remedy for injured patients. Indeed, under the PCS 2.0 system recourse through the traditional medical malpractice system is eliminated, instead requiring all applications to investigate medical injuries be channeled through the PCS 2.0 system beginning with an initial contact with a toll-free hotline. Awards for medical injuries are made not by medical malpractice insurers, by the state-based system itself.

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Under the PCS 2.0 model, a patient places a call into a state office that, in our model legislation, we have designated as the Office of Medical Review. The Office of Medical Review examines the patient's application to request an investigation to determine whether, on its face, the application constitutes a medical injury. After a thorough investigation of the application, an independent medical review panel reviews the information gathered and makes a final determination as to the existence of a medical injury. Based on this determination, the Office of Compensation, using a fee schedule adopted by the Board of Directors of the PCS 2.0. The PCS 2.0 system permits appeals on process grounds by either the patient or the practitioner to a State administrative law judge, with appeals to court to be consonant with the current workers compensation process. A quality improvement department reviews all claims submitted to the PCS 2.0 system.

II. Analysis

The PCS 2.0 system replaces traditional tort litigation and settlement practices with an administrative process that streamlines payments for medical injuries, expedites patient access to justice, and reduces the practice of defensive medicine by healthcare practitioners. Unlike the PCS 1.0 model, which streamlined but did not eliminate the traditional professional liability insurance industry, under PCS 2.0 all matters of compensation are handled through the PCS and not any third party. Whether payments made under the PCS 2.0 system qualify as "payments" to be reported to the NPDB depends on (1) whether or not the payments are made as a result of a "medical malpractice claim or action," and (2) whether there is a written claim or demand for payment.

As discussed above, the regulations implementing the NPDB require the reporting of a "payment" as a result of a "medical malpractice claim or action." The regulations then define a "medical malpractice claim or action" as (1) a written complaint or claim; (2) demanding payment; (3) based on a [practitioner's] failure to provide health care services; (4) and includes the filing of a cause of action based on the law of tort.

Unlike traditional malpractice claims in the adversarial tort system, a patient in the PCS 2.0 system does not file a written "complaint" or "claim," but rather places a verbal call into a toll-free hotline and files an "application" through an administrative process. Because the PCS 2.0 is a no-fault system, a patient does not allege medical malpractice, but only a medical injury. Therefore, the patient's filing is not based on the common law tort concept of negligence.

The implementing regulations require a payment be reported only for a payment made "in settlement of or in satisfaction in whole or in part of a claim or a judgment." Because

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payment is not made as a result of a "claim or judgment" but rather based on the finding of an independent, state-based administrative board that a "medical injury" has occurred, the payments made under the PCS 2.0 system are not for a "medical malpractice claim or action" and therefore are unlike those payments requiring reporting to the NPDB.

Finally, as detailed above, the regulations define a "medical malpractice claim or action" to include "a written claim or demand for payment..." As most recently detailed in the Department's letter to Oregon and Massachusetts in May 2014:

"The Department has consistently interpreted the phrase "written claim or demand for payment" as requiring a written claim or written demand for payment and excludes verbal demands for the purposes of defining a claim. Should a patient only verbally demand compensation from a provider, any resulting payment would not be reportable. A change in this policy would require rulemaking."

"Appropriate Medical Malpractice Payment Reporting to the NPDB in Light of Recent Medical Malpractice Reforms in Massachusetts and Oregon – DECISION," May 20, 2014 (Emphasis not added.) The Department goes on to note that, "if a provider or health care entity initiates the settlement and no written claim or demand for payment is made, then no report is required." Under the PCS 2.0, no claims or demands for payment are made and the "application" filed by the patient is made only verbally. The Office of Compensation, not the patient, is the entity that initiates the claim and settlement, not the patient. It is clear then, absent any written claim or demand, payments made under the PCS 2.0 do not occur as a result of a "medical malpractice claim or action" and are therefore not reportable.

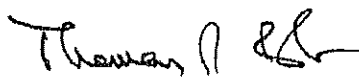
III. Conclusion

The triple-aim of the PCS 2.0 system makes it a unique, alternative solution to the current medical liability system. Unlike the current litigation system, which is adversarial, expensive, inefficient, and often does not connect injured patients with a settlement, the PCS 2.0 is a no-fault state-driven approach aimed at better aligning the interests of patients, doctors and taxpayers. As discussed above, a payment made to a patient under the PCS 2.0 is not a "medical malpractice payment," but rather a no-fault claim resulting from a verbal application and paid through a highly-regulated state-based administrative review process. Unlike payments reported to the NPDB which result from a written claim or judgment against a physician, a claim under the PCS 2.0 is made after a patient files an application with the PCS 2.0 and there is a no-fault finding of a medical injury. The application filed with the PCS 2.0 is not a "written claim or demand for payment" but rather a telephone call made to a toll-free hotline. As such, we do not believe a claim paid through the PCS 2.0 system would qualify for reporting to the NPDB.

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We are hereby requesting an opinion from the National Practitioner Data Bank with regard to whether or not a payment made under the Patients' Compensation System 2.0 is reportable. If any of our responses were inadequate or unclear, please do not hesitate to contact me. Thank you once again for your time and consideration.

Sincerely,



Thomas R. Barker, Partner
Foley Hoag, LLP

Not Responsive

From: Murry, Emily (Henehan) [mailto:emily.murry@mail.house.gov]
Sent: Friday, July 23, 2010 3:01 PM
To: Campbell, Shari (HRSA)
Subject: Rep. Price Questions for HRSA regarding NPDB and malpractice payment

Shari,

I wanted to reach out to you with help on answering the following questions we have regarding the NPDB (specifically, these are concerns a physician in Georgia has raised that Dr. Price is looking into). I believe you have already spoken with Cliff Binder at CRS on this issue (Leslie Atkinson is also aware of the general questions). In an effort to give more context and make sure our office is being clear in the questions we have related to the NPDB I have the following list of policy questions we would like to get answers to. If you need any more information or have any questions please don't hesitate to call me at 202-225-9286.

Thank you for your time.

Emily

Questions for HRSA regarding NPDB and malpractice payments with respect to the following areas:

1. "Reporting requirements" and the standing of a "reporting entity" with respect to 3rd parties having due process interests adverse to the reporting entity's clients.
2. "Reporting requirements" and state laws and bar rules governing insurance counsel
3. "Reporting requirements" and state insurance contract law especially "consent settle" clauses in the 48 states that authorize them for purposes of reducing frivolous claims

What would be the "reporting requirement" under the amended Health Care Quality Improvement Act of 1986 (HCQIA) and CFR given the following scenario:

- A. A 3rd party physician having no contract with a malpractice insurer (and thus not represented by the insurer's attorney) is listed in a blanket settlement agreement co-authored by the insurance company's attorney who releases 1st party insurance clients under a "corporate shield" by having them dismissed prior to the settlement agreement for no money then settling the malpractice claim under the corporate name.
- B. This settlement agreement is followed by dismissing the malpractice claim against all parties including the 3rd party physician.
- C. The claims against the 3rd party are presumed to be frivolous with respect to the 3rd party doctor
- D. In one instance, one of the claims released in the blanket settlement co-authored by the insurance attorney is a bad faith claim by the US government against the insurance company.
- E. The malpractice insurer then reports the entire settlement to the NPDB allocating its entirety to the 3rd party non-contracted physician
- F. This all occurs in a state that promotes "consent to settle" clauses in order to discourage payment for frivolous lawsuits. Under state law if contracts have such clauses, the insurer cannot legally settle with respect to claims against a particular physician without first obtaining consent from the accused physician (all 48 states except Maryland and Florida)

General questions for HRSA regarding the NPDB

1. Under the amended Health Care Quality Improvement Act of 1986 (HCQIA) and CFR, is it a well accepted rule that if a "reporting requirement" for the NPDB is not met then a report on the NPDB cannot be maintained?
2. Is the "reporting requirement" of a "reporting entity" dependent on the state laws where the case took place or was settled?
3. Can the malpractice insurer's requirement to report to the NPDB vary depending on the state laws where the case was initiated and settled; particularly with regard to respecting state law that authorizes consent to settle clauses?
4. When a malpractice insurance company settles a malpractice claim and the value of the settlement is not allocated to a specific party is there a "reporting requirement" to report all of the parties named in the suit, even if the settlement agreement was made for a frivolous claim and without "consent to settle" (a clause that requires a policyholder to first give consent before the company can settle a case on his or her behalf for purposes of reducing malpractice claims in states other than Florida and Maryland) from the parties?
5. If a settlement agreement (e.g. a contract entirely governing a particular settlement for \$1,000,000) where there are multiple causes of action and multiple parties released, does not allocate a specific amount to a specific doctor nor allocate an amount specifically to malpractice is it at the insurance companies discretion to report someone to the NPDB?
6. Would there be a "reporting requirement" that would compel or allow the insurer to at its discretion later allocate the entire sum in the settlement agreement to the malpractice claims (essentially regarding other valuable releases as worth 0) and to whichever doctor they decided to give a report?
7. Is there a "reporting requirement" that would compel or allow the settling attorney to allocate the value of such a settlement at his discretion, irrespective of state bar rules, contract law and constitutional questions posed; to a Doctor with whom the company has no contract of insurance and who has no representation or knowledge of the details of such a settlement?
8. What would be a subject's remedy with respect to deleting settlement information in the NPDB if it meets the "reporting requirements" and the rule that "... a subject may *not* dispute a report in order to protest a decision made by an insurer to settle a claim"?

The second issue involves the corporate status of physicians versus solo or independent practitioners and equal protection.

A malpractice insurer arranges with a plaintiff's attorney to have individual doctors dropped from a malpractice lawsuit, using the "corporate shield" (the practice of corporations removing practitioners' names from complains or settlement agreements to avoid reporting for no money). The malpractice insurer in turn settles in the name of the practitioners' corporation without reporting their clients, the individual practitioners, to the NPDB.

1. Can the insurer fail to report these physicians or the agreement to the NPDB while still reporting the name of the independent practitioner not covered by the insurer?
2. If one doctor can avoid being reported on the basis of corporate membership then how does HRSA reconcile this with requiring a report for an independent practitioner who has no corporate status for the same malpractice allegations?
3. If this is allowed is there an appeals process for providers that are caught in this situation?

General Policy Question

1. If this loophole (or does this not meet the reporting requirements) – where a malpractice insurer uses this case scenario as a template for protecting their clients (name a sole practitioner with tangential involvement in a malpractice case; negotiate a deal for the main defendant(s); settle and get the plaintiff(s) to drop all charges; hide the main defendants behind a corporate shield; and report the entire settlement to the medical boards/NPDB for the sole practitioner) – is in fact allowed, does the rule need to be clarified legislatively or can it be done through regulation at HRSA?
2. Can you provide data on how many times such an incident occurs?
3. Can you provide data on how many solo practitioners are reported in the NPDB for malpractice settlements as compared to doctors with corporate membership and/or in group practices?
4. Is there currently an appeals process for this type of situation?

424 Cannon Building
202-225-4501

