

**EXHIBIT 1**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,

*Plaintiffs,*

—v—

THE DEPARTMENT HEALTH AND HUMAN  
SERVICES, *et al.*,

*Defendants.*

Case No. 1:18-cv-2112

**DECLARATION OF MOLLY SMITH**

I, Molly Smith, state as follows under the pains and penalties of perjury. I am the Vice President, Coverage and State Issues Forum of the American Hospital Association (AHA), a Plaintiff in this action. The information set forth in this affidavit is based upon my personal knowledge.

1. The AHA is the national organization that represents and serves all types of hospitals, health care networks, and their patients and communities. Nearly 5,000 hospitals, health care systems, networks, other providers of care and 43,000 individual members come together to form the AHA. Through its advocacy and research efforts, the AHA ensures that its members' perspectives are heard and addressed in national health policy development, legislative and regulatory debates, and judicial actions.

2. Under the 340B Program, private prescription drug companies, as a condition of having their outpatient drugs covered through Medicaid, are required to enter into 340B Pharmaceutical Pricing Agreements with the Secretary of the Department of Health and Human Services (HHS) pursuant to which they must offer certain hospitals, community health centers and other federally funded clinics serving low-income patients ("340B providers") outpatient

drugs at or below an applicable, discounted, statutorily-determined price, referred to as the “ceiling price.”

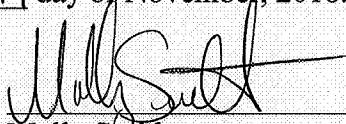
3. This action challenges the repeated delays in HHS’s implementation of a final rule, published January 5, 2017 (the “Final 340B Rule”), that would implement amendments to the 340B program enacted by Congress in 2010. Specifically, the Final 340B Rule would require HHS to provide 340B providers with access to ceiling prices (through an HHS website); adopt a methodology for calculating ceiling prices for new drugs and in circumstances when the price for a given drug is increased faster than the rate of inflation; and impose monetary penalties on drug companies that overcharge 340B providers.

4. Many of the AHA’s members are 340B providers. The delay of each aspect of the Final 340B Rule causes harm to the 340B providers among the AHA’s members. For example, the current lack of access to ceiling prices and the lack of a clear, transparent methodology means 340B providers do not even know whether they are being overcharged, creating uncertainty and unpredictability. Moreover, many 340B providers have reason to believe they have in fact been overcharged, based among other things on reports of the HHS Office of the Inspector General, which found that drug companies had overcharged 340B providers.

5. Each aspect of the Final 340B Rule, independently and collectively, would help remedy these harms. Publication of ceiling prices, imposition of a clear methodology for new drugs and drugs with fast-rising prices, and the threat of civil monetary penalties for drug companies that overcharge 340B providers, would not only allow 340B providers to know whether and to what extent they have been and/or will have been overcharged, but would permit them to seek refunds for such overpayments, and would deter drug companies from overcharging 340B providers in the first place.

6. By seeking to improve the accuracy and transparency of 340B ceiling prices and providing a mechanism for the imposition of penalties for non-compliance, this action seeks to further interests of its members that are germane to the AHA's organizational purpose.

Signed under penalty of perjury this 19 day of November, 2018.

A handwritten signature in black ink, appearing to read "Molly Smith", written over a horizontal line.

Molly Smith

Vice President, Coverage and State Issues Forum  
American Hospital Association

**EXHIBIT 2**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,

*Plaintiffs,*

–v–

THE DEPARTMENT HEALTH AND HUMAN  
SERVICES, *et al.*,

*Defendants.*

Case No. 1:18-cv-2112

**DECLARATION OF BRUCE SIEGEL**

I, Bruce Siegel, MD, MPH, state as follows under the penalties of perjury. I am the President and CEO of America’s Essential Hospitals (AEH), a Plaintiff in this action. The information set forth in this affidavit is based upon my personal knowledge.

1. AEH is a national, not-for-profit association headquartered in Washington, D.C. AEH is a champion for hospitals and health systems dedicated to high-quality care for all, including the most vulnerable. Since 1981, AEH has initiated, advanced, and preserved programs and policies that help these hospitals ensure access to care. Its more than 325 hospital members are vital to their communities, providing primary care through trauma care, disaster response, health professional training, research, public health programs, and other services.

2. Under the 340B Program, private prescription drug companies, as a condition of having their outpatient drugs covered through Medicaid, are required to enter into 340B Pharmaceutical Pricing Agreements with the Secretary of the Department of Health and Human Services (HHS) pursuant to which they must offer certain hospitals, community health centers and other federally funded clinics serving low-income patients (“340B providers”) outpatient

drugs at or below an applicable, discounted, statutorily-determined price, referred to as the “ceiling price.”

3. This action challenges the repeated delays in HHS’s implementation of a final rule, published January 5, 2017 (the “Final 340B Rule”), that would implement amendments to the 340B program enacted by Congress in 2010. Specifically, the Final 340B Rule would require HHS to provide 340B providers with access to ceiling prices (through an HHS website); adopt a methodology for calculating ceiling prices for new drugs and in circumstances when the price for a given drug is increased faster than the rate of inflation; and impose monetary penalties on drug companies that overcharge 340B providers.

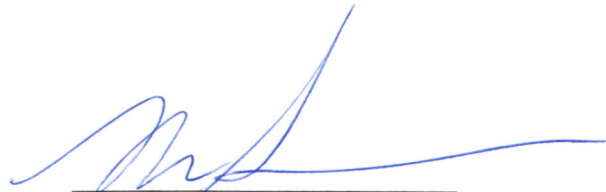
4. Almost all of AEH’s members are 340B providers. The delay of each aspect of the Final 340B Rule causes harm to the 340B providers among the AEH’s members. For example, the current lack of access to ceiling prices and the lack of a clear, transparent methodology means 340B providers do not even know whether they are being overcharged, creating uncertainty and unpredictability. Moreover, many 340B providers have reason to believe they have in fact been overcharged, based among other things on reports of the HHS Office of the Inspector General, which found that drug companies had overcharged 340B providers.

5. Each aspect of the Final 340B Rule, independently and collectively, would help remedy these harms. Publication of ceiling prices, imposition of a clear methodology for new drugs and drugs with fast-rising prices, and the threat of civil monetary penalties for drug companies that overcharge 340B providers, would not only allow 340B providers to know whether and to what extent they have been and/or will have been overcharged, but would permit

them to seek refunds for such overpayments, and would deter drug companies from overcharging 340B providers in the first place.

6. By seeking to improve the accuracy and transparency of 340B ceiling prices and providing a mechanism for the imposition of penalties for non-compliance, this action seeks to further interests of its members that are germane to the AEH's organizational purpose.

Signed under penalty of perjury this 19<sup>th</sup> day of November, 2018.



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Bruce Siegel, MD, MPH  
President and CEO  
America's Essential Hospitals

**EXHIBIT 3**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,

*Plaintiffs,*

–v–

THE DEPARTMENT HEALTH AND HUMAN  
SERVICES, *et al.*,

*Defendants.*

Case No. 1:18-cv-2112

**DECLARATION OF JANIS M. ORLOWSKI, MD**

I, Janis M. Orlowski, state as follows under the pains and penalties of perjury. I am the Chief Health Care Officer of the Association of American Medical Colleges (AAMC), a Plaintiff in this action. The information set forth in this affidavit is based upon my personal knowledge.

1. AAMC is a national, not-for-profit association headquartered in Washington, D.C. AAMC is dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its membership consists of all 152 accredited U.S. and 17 accredited Canadian medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies.

2. Under the 340B Drug Pricing Program, private prescription drug companies, as a condition of having their outpatient drugs covered through Medicaid, are required to enter into 340B Pharmaceutical Pricing Agreements with the Secretary of the Department of Health and Human Services (HHS) pursuant to which they must offer certain hospitals, community health centers and other federally funded clinics serving low-income patients (“340B providers”) outpatient drugs at or below an applicable, discounted, statutorily-determined price, referred to as the “ceiling price.”

3. This action challenges the repeated delays in HHS's implementation of a final rule, published January 5, 2017 (the "Final 340B Rule"), that would implement amendments to the 340B program enacted by Congress in 2010. Specifically, the Final 340B Rule would require HHS to provide 340B providers with access to ceiling prices (through an HHS website); adopt a methodology for calculating ceiling prices for new drugs and in circumstances when the price for a given drug is increased faster than the rate of inflation; and impose monetary penalties on drug companies that overcharge 340B providers.

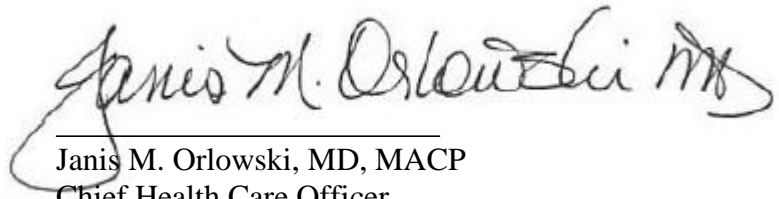
4. Many of the AAMC's hospital members are 340B providers. The delay of each aspect of the Final 340B Rule causes harm to the 340B providers among the AAMC's members. For example, the current lack of access to ceiling prices and the lack of a clear, transparent methodology means 340B providers do not even know whether they are being overcharged, creating uncertainty and unpredictability. Moreover, many 340B providers have reason to believe they have in fact been overcharged, based among other things on reports of the HHS Office of the Inspector General, which found that drug companies had overcharged 340B providers.

5. Each aspect of the Final 340B Rule, independently and collectively, would help remedy these harms. Publication of ceiling prices, imposition of a clear methodology for new drugs and drugs with fast-rising prices, and the threat of civil monetary penalties for drug companies that overcharge 340B providers, would not only allow 340B providers to know whether and to what extent they have been and/or will have been overcharged, but would permit them to seek refunds for such overpayments, and would deter drug companies from overcharging 340B providers in the first place.

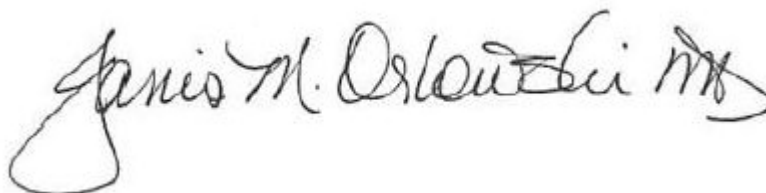


6. By seeking to improve the accuracy and transparency of 340B ceiling prices and providing a mechanism for the imposition of penalties for non-compliance, this action seeks to further interests of its members that are germane to the AAMC's organizational purpose.

Signed under penalty of perjury this 21<sup>st</sup> day of November, 2018.

A handwritten signature in black ink, reading "Janis M. Orlowski MD". The signature is written in a cursive style with a large loop at the end of the "s".

Janis M. Orlowski, MD, MACP  
Chief Health Care Officer  
The Association of American Medical Colleges

A second handwritten signature in black ink, identical to the one above, reading "Janis M. Orlowski MD".

**EXHIBIT 4**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,

*Plaintiffs,*

–v–

THE DEPARTMENT HEALTH AND HUMAN  
SERVICES, *et al.*,

*Defendants.*

Case No. 1:18-cv-2112

**DECLARATION OF MAUREEN TESTONI**

I, Maureen Testoni, state as follows under the penalties of perjury. I am the Interim President and Chief Executive Officer of 340B Health, a Plaintiff in this action. The information set forth in this affidavit is based upon my personal knowledge.

1. 340B Health is a national, not-for-profit organization headquartered in Washington, D.C. The organization was founded in 1993 to advocate on behalf of 340B covered entities, and to increase the affordability and accessibility of pharmaceutical and clinical care for the nation's poor and underserved populations. 340B Health monitors, educates, and serves as an advocate on federal legislative and regulatory issues related to drug pricing and other pharmacy matters that affect safety net providers. 340B Health represents more than 1,300 public and private nonprofit hospitals and health systems that participate in the federal 340B drug pricing program.

2. Under the 340B Program, private prescription drug companies, as a condition of having their outpatient drugs covered through Medicaid, are required to enter into 340B Pharmaceutical Pricing Agreements with the Secretary of the Department of Health and Human Services (HHS) pursuant to which they must offer certain hospitals, community health centers

and other federally funded clinics serving low-income patients (“340B providers”) outpatient drugs at or below an applicable, discounted, statutorily-determined price, referred to as the “ceiling price.”

3. This action challenges the repeated delays in HHS’s implementation of a final rule, published January 5, 2017 (the “Final 340B Rule”), that would implement amendments to the 340B program enacted by Congress in 2010. Specifically, the Final 340B Rule would require HHS to provide 340B providers with access to ceiling prices (through an HHS website); adopt a methodology for calculating ceiling prices for new drugs and in circumstances when the price for a given drug is increased faster than the rate of inflation; and impose monetary penalties on drug companies that overcharge 340B providers.

4. All of the 340B Health’s members are 340B providers. The delay of each aspect of the Final 340B Rule causes harm to 340B Health’s members. For example, the current lack of access to ceiling prices and the lack of a clear, transparent methodology means 340B providers do not even know whether they are being overcharged, creating uncertainty and unpredictability. Moreover, many 340B providers have reason to believe they have in fact been overcharged, based among other things on reports of the HHS Office of the Inspector General, which found that drug companies had overcharged 340B providers.

5. Each aspect of the Final 340B Rule, independently and collectively, would help remedy these harms. Publication of ceiling prices, imposition of a clear methodology for new drugs and drugs with fast-rising prices, and the threat of civil monetary penalties for drug companies that overcharge 340B providers, would not only allow 340B providers to know whether and to what extent they have been and/or will have been overcharged, but would permit

them to seek refunds for such overpayments, and would deter drug companies from overcharging 340B providers in the first place.

6. By seeking to improve the accuracy and transparency of 340B ceiling prices and providing a mechanism for the imposition of penalties for non-compliance, this action seeks to further interests of its members that are germane to the 340B Health's organizational purpose.

Signed under penalty of perjury this 19<sup>th</sup> day of November, 2018.

A handwritten signature in black ink, appearing to read "Maureen Testoni". The signature is fluid and cursive, with a distinct dot over the 'i'.

Maureen Testoni  
Interim President and Chief Executive Officer  
340B Health

**EXHIBIT 5**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,

*Plaintiffs,*

–v–

THE DEPARTMENT HEALTH AND HUMAN  
SERVICES, *et al.*,

*Defendants.*

Case No. 1:18-cv-2112

**DECLARATION OF GENESIS HEALTHCARE SYSTEM**

I, **MATT PERRY**, state as follows under the pains and penalties of perjury. I am the **PRESIDENT AND CHIEF EXECUTIVE OFFICER** of Genesis HealthCare System (Genesis), a Plaintiff in this action. The information set forth in this affidavit is based upon my personal knowledge.

1. Genesis is an integrated health care delivery system based in Zanesville, Ohio. Genesis is the largest health care provider in its rural, economically challenged six-county region. Genesis is comprised of an acute care hospital that serves as a rural referral center and includes a 200-provider medical group and provides a multitude of ambulatory health services. Genesis is the regional safety net provider for the 235,000 residents of their six-county service area.

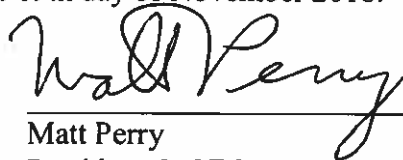
2. Genesis is a member of 340B Health and the American Hospital Association and participates in the 340B Program. This action challenges the repeated delays in HHS's implementation of a final rule, published January 5, 2017 (the "Final 340B Rule"), that would implement amendments to the 340B program. Specifically, the Final 340B Rule would require HHS to provide 340B providers like Genesis with access to ceiling prices; adopt a methodology

for calculating ceiling prices for new drugs and in circumstances when the price for a given drug is increased faster than the rate of inflation; and impose monetary penalties on drug companies that overcharge 340B providers.

3. The delay of each aspect of the Final 340B Rule causes harm to Genesis. For example, the current lack of access to ceiling prices and the lack of a clear, transparent methodology means Genesis does not even know whether it is being overcharged, creating uncertainty and unpredictability. Nonetheless, Genesis has reason to believe it has in fact been overcharged, based among other things on reports of the HHS Office of the Inspector General, which found that drug companies had overcharged 340B providers.

4. Each aspect of the Final 340B Rule, independently and collectively, would help remedy these harms. Publication of ceiling prices, imposition of a clear methodology for new drugs and drugs with fast-rising prices, and the threat of civil monetary penalties for drug companies that overcharge 340B providers like Genesis, would allow Genesis to know whether and to what extent it has been or will be overcharged, would permit Genesis to seek refunds for such overpayments, and would deter drug companies from overcharging 340B providers like Genesis in the first place.

Signed under penalty of perjury this 19th day of November 2018.

A handwritten signature in black ink, appearing to read "Matt Perry", written over a horizontal line.

Matt Perry  
President & CEO  
Genesis Healthcare System

**EXHIBIT 6**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,

*Plaintiffs,*

–v–

THE DEPARTMENT HEALTH AND HUMAN  
SERVICES, *et al.*,

*Defendants.*

Case No. 1:18-cv-2112

**DECLARATION OF BENJAMIN ANDERSON**

I, Benjamin Anderson, state as follows under the pains and penalties of perjury. I am the Chief Executive Officer of Kearny County Hospital (KCH), a Plaintiff in this action. The information set forth in this affidavit is based upon my personal knowledge.

1. KCH was founded in 1952 and has been operated as a county hospital since 1976. KCH provides inpatient and outpatient hospital care, emergency medicine and primary care annually to patients from 20 counties in Kansas and Colorado. Kearny County delivers approximately 350 babies per year, with one-way commutes for those patients being up to 120 miles.

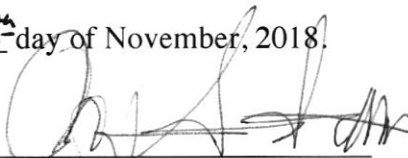
2. KCH is a member of the American Hospital Association and participates in the 340B Program. This action challenges the repeated delays in HHS's implementation of a final rule, published January 5, 2017 (the "Final 340B Rule"), that would implement amendments to the 340B program. Specifically, the Final 340B Rule would require HHS to provide 340B providers like KCH with access to ceiling prices; adopt a methodology for calculating ceiling prices for new drugs and in circumstances when the price for a given drug is increased faster than the rate of inflation; and impose monetary penalties on drug companies that overcharge 340B

providers.

3. The delay of each aspect of the Final 340B Rule causes harm to KCH. For example, the current lack of access to ceiling prices and the lack of a clear, transparent methodology means KCH does not even know whether it is being overcharged, creating uncertainty and unpredictability. Moreover, KCH has reason to believe it has in fact been overcharged, based among other things on reports of the HHS Office of the Inspector General, which found that drug companies had overcharged 340B providers.

4. Each aspect of the Final 340B Rule, independently and collectively, would help remedy these harms. Publication of ceiling prices, imposition of a clear methodology for new drugs and drugs with fast-rising prices, and the threat of civil monetary penalties for drug companies that overcharge 340B providers like KCH, would not only allow KCH to know whether and to what extent it has been and/or will have been overcharged, but would permit KCH to seek refunds for such overpayments, and would deter drug companies from overcharging 340B providers like KCH in the first place.

Signed under penalty of perjury this 16<sup>th</sup> day of November, 2018.



Benjamin Anderson  
Chief Executive Officer  
Kearny County Hospital



**EXHIBIT 7**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,

*Plaintiffs,*

–v–

THE DEPARTMENT HEALTH AND HUMAN  
SERVICES, *et al.*,

*Defendants.*

Case No. 1:18-cv-2112

**DECLARATION OF JONATHAN REYNOLDS**

I, Jonathan Reynolds, state as follows under the pains and penalties of perjury. I am the Senior Director of Pharmacy of Rutland Regional Medical Center (RRMC), a Plaintiff in this action. The information set forth in this affidavit is based upon my personal knowledge.

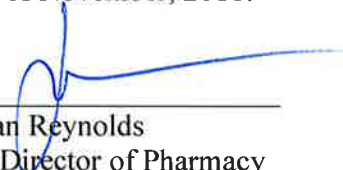
1. RRMC is headquartered in Rutland, Vermont, is the largest community hospital in Vermont, and the second-largest Vermont hospital overall, and has been providing high-quality healthcare for over 100 years. Rutland Regional services an aging community with a large proportion of Medicare beneficiaries.

2. RRMC is a member of 340B Health and the American Hospital Association and participates in the 340B Program. This action challenges the repeated delays in HHS's implementation of a final rule, published January 5, 2017 (the "Final 340B Rule"), that would implement amendments to the 340B program. Specifically, the Final 340B Rule would require HHS to provide 340B providers like RRMC with access to ceiling prices; adopt a methodology for calculating ceiling prices for new drugs and in circumstances when the price for a given drug is increased faster than the rate of inflation; and impose monetary penalties on drug companies that overcharge 340B providers.

3. The delay of each aspect of the Final 340B Rule causes harm to RRMC. For example, the current lack of access to ceiling prices and the lack of a clear, transparent methodology means RRMC does not even know whether it is being overcharged, creating uncertainty and unpredictability. Nonetheless, RRMC has reason to believe it has in fact been overcharged, based among other things on reports of the HHS Office of the Inspector General, which found that drug companies had overcharged 340B providers.

4. Each aspect of the Final 340B Rule, independently and collectively, would help remedy these harms. Publication of ceiling prices, imposition of a clear methodology for new drugs and drugs with fast-rising prices, and the threat of civil monetary penalties for drug companies that overcharge 340B providers like RRMC, would allow RRMC to know whether and to what extent it has been or will be overcharged, would permit RRMC to seek refunds for such overpayments, and would deter drug companies from overcharging 340B providers like RRMC in the first place.

Signed under penalty of perjury this 20 day of November, 2018.



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Jonathan Reynolds  
Senior Director of Pharmacy  
Rutland Regional Medical Center