HEALTHTRUST®
UNIVERSITY CONFERENCE

CELEBRATING 25 TWENTY-FIVE YEARS

340B In The Field

Steven Schnelle, JD

Partner, McDermott Will & Emery LLP

Disclosures

The presenter has no real or perceived conflicts of interest related to this presentation

Note: The content presented is for informational purposes only and is based upon the presenter(s) knowledge and opinion. It should not be relied upon without independent consultation with and verification by appropriate professional advisors. Individuals and organizations shall have sole responsibility for any actions taken in connection with the content herein. HealthTrust, the program presenter(s) and their employers expressly disclaim any and all warranties as to the content as well as any liability resulting from actions or omissions of any individual or organization in reliance upon the content.

This program may contain the mention of suppliers, brands, products, services or drugs presented in a case study or comparative format using evidence-based research. Such examples are intended for educational and informational purposes and should not be perceived as an endorsement of any particular supplier, brand, product, service or drug.

Learning Objectives

At the end of this session, participants should be able to:

1. Recall the current 340B legal landscape & the effect manufacturer non-participation may impose.
2. Recognize 340B program growth opportunities & 340B best practices.
3. Identify solutions to understand how to mitigate escalating issues within the 340B space.

Overview

- 340B Program Compliance
- Child Site Eligibility & Updates
- Contract Pharmacy Eligibility & Updates
- Patient Eligibility & Updates
- Billing, Financial Assistance & Reporting
- Inflation Reduction Act
- Looking Ahead

340B PROGRAM COMPLIANCE

Source: Getty Images. Used with permission of HealthTrust.

340B Program History & Overview

- Enacted in 1992
- Significant changes in 2010
  - Contract pharmacy expansion
  - Affordable Care Act expansion
- Approximately 13,000 participating entities (“Covered Entities”)
  - Federal grantees & contactors (~80% of Covered Entities)
  - Non-profit & government hospitals (~20% of Covered Entities)
- Approximately $44 Billion in drug purchases
  - Approximately $37 Billion made by hospital Covered Entities

Citations:
- Government Accountability Office: https://www.gao.gov/assets/gao-21-107.pdf
- Health Resources and Services Administration: https://www.hrsa.gov/opa/updates/2021-340b-covered-entity-purchases

340B Program Compliance

- Provider entity eligibility to participate in the 340B Program
  - Grantee/contractor types
  - Hospital types & DSH threshold
- Medicaid duplicate discount prohibition
- Diversion prohibition
- On-line database of Covered Entity information
- GPO Prohibition and/or Orphan Drug exclusion

Other Legal/Compliance Considerations

- Child-site eligibility
- Patient eligibility
- Medicaid billing/coding for 340B drugs
- Medicare billing/coding for 340B drugs
- Terms of hospital contract with state or local government for eligibility
- Pharmacy patient financial assistance programs
- State pharmacy laws

What do you think?

Polling Question #1

HRSA has published many notices in the Federal Register & on its website explaining how to comply with the 340B Program. Is that guidance legally binding on covered entities & manufacturers?

A. Yes, covered entities & manufacturers must comply with HRSA's compliance instructions.

B. No, this guidance is voluntary.

C. Maybe, depending on a number of factors.

Answer

Polling Question #1

C. Maybe, depending on a number of factors.

- Any HRSA enforcement action must be authorized by the 340B Statute.
- HRSA can interpret the 340B Statute & issue guidance explaining how it interprets the statute.
- However, HRSA cannot establish entirely new legal standards through guidance, & interpretations that are inconsistent with the plain meaning of the 340B Statute or its intent will be highly scrutinized.

CHILD SITES

Source: Getty Images. Used with permission of HealthTrust.

Criteria to Meet Child Site Eligibility

- 340B Statute does not outline requirements for 340B child-site eligibility
- “Child-site” locations best practice:
  - Must be part of the Medicare-certified & enrolled hospital entity (i.e., must meet Medicare provider-based rules)
  - Must be on a hospital’s most-recently filed Medicare cost report to be registered in on-line 340B database (OPAIS)

Source: Getty Images. Used with permission of HealthTrust.

Citations:
- 340B Statute: https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf
- 59 Fed. Reg. 47884 (September 19, 1994): https://www.hrsa.gov/sites/default/files/hrsa/opa/outpatient-hospital-facilities.pdf

HRSA Notice

- In May 2023, HRSA unexpectedly revoked a policy that allowed for use of 340B drugs for patients at unregistered child sites of covered entities
- In October, HRSA issued a Notice to remind 340B Program covered entities of the child site eligibility criteria
- The notice & current HRSA policy are subject to an on-going legal challenge by 44 hospitals

Source: Getty Images. Used with permission of HealthTrust.

Citations:
- October 2023 Notice: https://www.govinfo.gov/content/pkg/FR-2023-10-27/pdf/2023-23702.pdf

CONTRACT PHARMACIES

CE Credit Deadline: 09/30/24

Source: Getty Images. Used with permission of HealthTrust.

340B Contract Pharmacy

340B covered entities may dispense 340B drugs directly or through contractual arrangements with pharmacies (“contract pharmacies”)

- Contract pharmacies typically operate under a “replenishment” or “virtual” inventory model
  - Drugs are dispensed from common drug stock & restocked with 340B pricing for eligible drugs
- Claims for 340B drugs are generally identical to claims for all other drugs
  - Eligibility for 340B pricing is typically determined after dispensing
- Contract pharmacies bill payors & remit payments back to covered entity less a dispensing fee

Citations:

- 75 Fed. Reg. 10272 (March 5, 2010): https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf

HRSA Guidelines – Best Practices

HRSA reviews 340B contract pharmacy arrangements under its 2010 Notice guidelines

- Contract pharmacy must be registered and active in OPAIS
- Covered entity purchases and maintains title to drug
- Patient retains freedom to choose pharmacy provider
- Patient eligibility verification system
- Establish and maintain a tracking system to prevent diversion

Citations:
- 340B Statute: https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf

Manufacturer Restrictions

- Drug manufacturers are not required to provide a 340B discount & a Medicaid drug rebate on the same drug
- Duplicate discounts are typically prevented by excluding Medicaid claims from contract pharmacy arrangements
- 340B Program does not prohibit contractual duplicate discounts
  - Rebates that are voluntarily offered by manufacturers under commercial payor & PBM agreements

Citations:
- 340B Statute: https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf

Manufacturer Restrictions, cont'd.

- Beginning in mid-2020, certain manufacturers began restricting access to 340B drugs dispensed through contract pharmacy arrangements
  - Currently 30 manufacturers
  - Most require submission of contract pharmacy dispensing data
  - Most allow for exception of designation of a single contract pharmacy
  - Some allow for exception of designation of covered entity/system owned retail pharmacy
- Expect more manufacturers to add restrictions & the restrictions to become increasingly broad

Citations:
- National Association of Community Health Centers: https://www.nachc.org/wp-content/uploads/2023/11/340b-restrictions-summary-chart1_.pdf

HRSA Advisory Opinion

Litigation

- Following release of HRSA Advisory Opinion prohibiting restrictions on sales of 340B drugs & corresponding enforcement letters, 10 manufacturers have brought claims against HHS in federal court
- Four cases pending in D.C. District Court
- Two cases pending in federal Appeals Courts
- One case decided in Third Circuit Court of Appeals
  - Court ruled in favor of three manufacturers & found that HHS cannot take enforcement action against manufacturers for imposing 340B sales restrictions that are not prohibited by the statute

Citations:
- 340B Litigation Tracker: https://www.mcdermottplus.com/340b-litigation-tracker-registration/

Senate HELP Committee Investigation

On January 17, 2024, Senator Bill Cassidy, ranking member of the Health, Education, Labor & Pensions (HELP) Committee, sent letters seeking information from CVS Health & Walgreens on their 340B Program participation

- Part of an on-going investigation into 340B Program revenue use
- Intent is to better understand whether that revenue results in direct benefits for patients

Citations:

- HELP Committee: https://www.help.senate.gov/ranking/newsroom/press/ranking-member-cassidy-seeks-information-from-major-contract-pharmacies-as-part-of-ongoing-340b-investigation

PATIENT ELIGIBILITY

Source: Getty Images. Used with permission of HealthTrust.

Elements of Patient Eligibility

- 340B Statute limits resale & transfer of 340B drugs to “patient[s] of the entity”
- 1996 guidance further defines “patient”
  - Visit with a Covered Entity (CE) provider
  - CE assumes responsibility for & maintains records of the patients care
  - For grantee CEs, care must be within scope of their qualifying grant
- Providing 340B drug to anyone other than a “patient” is diversion
  - May be subject to refund of the 340B discount amount to the manufacturer
  - May result in removal from the 340B Program if found to be knowing, intentional, systemic & egregious

Citations:
Patient Definition: https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf

Genesis Healthcare v. Becerra

- *Genesis* filed suit against HRSA following 2017 audit & attempted removal from the 340B Program
- HRSA interpreted "patient of the entity" to mean that a covered entity "initiated the healthcare services resulting in the prescription"
- South Carolina District Court enjoined HRSA from enforcing this interpretation against Genesis
- Court applied "plain or common meaning" of the term "patient," which under all definitions cited requires a healthcare service be provided by the covered entity to the individual qualifying as a "patient" of the covered entity

Citations:
- *Genesis HealthCare v. Becerra*: https://www.ca4.uscourts.gov/opinions/201701.P.pdf

Genesis Healthcare v. Becerra, cont'd.

- Decision directly applies only to *Genesis* & HRSA
- HRSA is not prohibited by the decision from enforcing the narrower "patient" definition against other covered entities
- Other courts may not agree with the South Carolina District Court's reasoning or conclusion
- Reasoning & conclusion may
  - Be persuasive to other courts
  - Serve as the basis for a covered entity's interpretation of the statutory term "patient"
  - Provide a structure for interpreting other undefined terms in the 340B Statute

Post-*Genesis* HRSA Audits

Audits continue in definition of the "patient"

- HRSA emphasizes that the *Genesis* decision is applicable solely to *Genesis* Health Care.
- Accordingly, HRSA has indicated that it will resume audits of the "patient" definition.
- We are already seeing final reports being issued with HRSA's pre-*Genesis* interpretation.

What do you think?

Polling Question #2

How does a covered entity appeal an HRSA audit finding?

A. HRSA audit findings are not appealable
B. Submit a Written Notice of Disagreement to HRSA
C. File a lawsuit in federal court
D. Both B & C

Answer

Polling Question #2

D. Both B & C

- HRSA audits typically result in a “Final Report” that gives the covered entity an opportunity to submit a Written Notice of Disagreement.
- HRSA will then issue another Final Report that takes into consideration the covered entity’s comments.
- If the covered entity believes the Final Report’s findings are unlawful, it may file a lawsuit in federal court.

BILLING, FINANCIAL ASSISTANCE & REPORTING

Source: Getty Images. Used with permission of HealthTrust.

CMS OPPS Repayment

- In November 2023, CMS issued a final rule establishing a remedy to the OPPS payment cuts to 340B drugs from 2018 to 2022
  - Hospitals received lump-sum payments for the total amount due (unless disputed)
  - Budget Neutrality—payments for non-drug items & services to all OPPS hospitals will be reduced by 0.5% starting CY2026 for approx. 16 years
- Payment cut remedy did not remove 340B modifier requirements for Medicare claims – Modifier “TB” required on all claims for 340B drugs, beginning January 1, 2025

Citations:
- Hospital OPPS Final Rule: https://www.govinfo.gov/content/pkg/FR-2023-07-31/pdf/2023-14768.pdf

Baptist Health v. Humana

- Baptist Health filed suit against several Humana entities under state contract law for failing to make lump-sum payment similar to CMS
- The underpayments are connected to Humana's mirroring of CMS Medicare fee-for-service payments from 2018 to 2022
- Medicare Advantage (MA) plan payments were "out of the scope of [the OPPS payment remedy] final rule"
- The issue of MA plans was raised in comments to the final rule by various health systems & associations
- CMS references the 340B payment cuts & remedy in the 2025 MA plan year Advance Notice

Citations:

- Baptist Health v. Humana Docket: https://dockets.justia.com/docket/alabama/almdce/2:2024cv00077/82283

What do you think?

Question #3

Who sets Medicaid reimbursement policy for 340B drugs?

A. HRSA
B. CMS
C. State Medicaid Programs
D. B & C
E. All of the above

Answer

Question #3

D. B & C

- HRSA is authorized to administer the 340B Program, which fundamentally is a drug purchasing program. However, 340B Program pricing is related to reimbursement due to the duplicate discount prohibition
- CMS has promulgated regulations & guidance establishing Actual Acquisition Cost requirements for Medicaid state agencies to implement
- Medicaid state agencies must implement federal requirements but also have areas of discretion (e.g., coding modifiers for 340B drugs)

Medicaid Billing for 340B Drugs

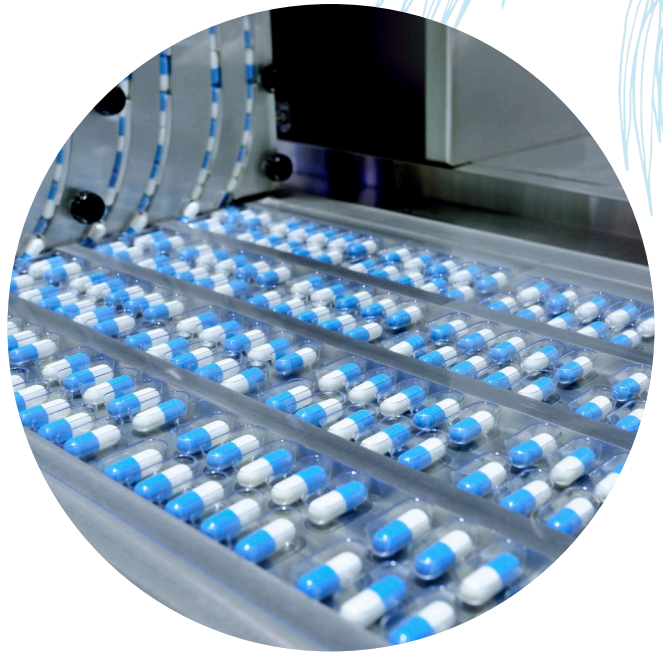
- Medicaid “actual acquisition cost” (AAC) billing requires identifying 340B drugs & reporting the “actual” 340B acquisition cost
- Failure to identify drugs as 340B drugs or to accurately report the 340B acquisition cost may result in overpayments
- Suspected Medicaid overpayments must be investigated & refunded within 60 days of quantification
- Failure to investigate or failure to timely refund may result in “reverse” false claims act liability for retained overpayments

Citations:

- Centers for Medicare and Medicaid Services Bulletin: https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf

False Claims Act Settlements

- In 2020, Memorial Care entered into a $30 million settlement agreement with U.S. Department of Justice (DOJ), Health and Human Services Office of Inspector General (HHS OIG) & California Department of Justice (CA DOJ) for over-billing Medi-Cal for 340B drugs & failing to return the overpayments
- In January 2024, Pomona Valley Medical Center reached a settlement of $2.1 million with similar facts
- Expect increased activity in Medicaid 340B overpayment self-disclosures, qui tams & government settlements



Source: Getty Images. Used with permission of HealthTrust.

Citations:
- Memorial Care Settlement: https://www.justice.gov/usao-cdca/pr/oc-based-health-care-organization-agrees-pay-over-315-million-settle-claims-it
- Pomona Valley Medical Center Settlement: https://www.justice.gov/usao-cdca/pr/pomona-hospital-agrees-pay-more-2-million-after-self-reporting-overbilling-medi-cal

Pharmacy Patient Financial Assistance Programs

- Many covered entities are implementing pharmacy-specific patient financial assistance programs
- Often supported by 340B savings or tied to 340B pricing on drugs eligible for assistance
- Present potential risks under the federal anti-kickback statute, the federal beneficiary inducements civil monetary penalty law, and/or state equivalent laws
- There are “safe harbors,” but most policies need to be evaluated based on a “facts & circumstances” test

INFLATION REDUCTION ACT

Source: Getty Images. Used with permission of HealthTrust.

Inflation Reduction Act (IRA)

Nonduplication with 340B Ceiling Price:
"The manufacturer of a selected drug…

- 1) Shall not be required to provide access to the maximum fair price under subsection (a)(3), with respect to such selected drug &maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act &the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug; &
- 2) Shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for such selected drug." [Sec. 1193(d)]

Citation:
- Inflation Reduction Act of 2022: https://www.irs.gov/inflation-reduction-act-of-2022

LOOKING AHEAD

Source: Getty Images. Used with permission of HealthTrust.

Restrictions on 340B

- Manufacturers
  - Currently 30 manufacturers restrict 340B purchases
  - Could further expand beyond contract pharmacy dispensing restrictions
  - Relief not expected without additional legislation or litigation
- Congress
  - PATIENT Act – Requires additional pharmacy reporting
  - Bucshon Bill – Requires reporting use of savings by child site
- HRSA
  - Continued requests for regulatory authority, including oversight of savings
  - History of policy decisions that are not covered entity-friendly

State Laws

- Louisiana, Arkansas & West Virginia have enacted laws prohibiting manufacturer 340B contract pharmacy restrictions
  - LA & AR laws are subject to on-going litigation
  - AR law recently upheld by 8th Circuit
  - 19 states have similar pending legislation
- 30 states (including California) have laws that bar pharmacy benefit managers from discriminating based on 340B status
- 3 states have passed laws requiring CE data reporting/transparency
  - 2 states have pending/proposed legislation

SUSTAIN 340B Act

- Bipartisan group of six senators released a discussion draft of proposed 340B legislation – “SUSTAIN 340B Act”
- The draft seeks to clarify the use of contract pharmacies & the definition of “child site” & “patient,” among other changes
- Would require additional data reporting & impose a “user fee”
- The draft was accompanied by a supplemental Request for Information (RFI), including several questions & topics for 340B stakeholder input
  - Responses were due April 1, 2024

Citations:

- SUSTAIN 340B Act Discussion Draft: https://www.thune.senate.gov/public/_cache/files/5e99f492-7a5e-428d-a25e-f4722cfd4b38/26132C0D072A3EF9EB32FB58CFEF5819.340b-discussion-draft-explanatory-document-and-subsequent-rfi.pdf

340B Access Act

(Reps. Bucshon, Carter & Harshbarger)

- 340B Affording Care for Communities & Ensuring a Strong Safety-Net Act (340B ACCESS Act) introduced on May 28, 2024
- The bill attempts to
  - Clarify the intent of the 340B Program
  - Codify a prescription-by-prescription patient definition
  - Impose restrictions on contract pharmacies and child site eligibility
  - Increase transparency
- Described as a “pharmaceutical industry wish list”
- Referred to the Committee on Energy & Commerce

Citations:

- 340B Access Act: https://www.nachc.org/wp-content/uploads/2024/05/340B-ACCESS-Act-Text.pdf

Solutions – Best Practices to Mitigate Issues

- Regularly monitor updates in the 340B Program
- Monitor compliance of internal programs with guidance from government agencies and courts
- Confer with third parties to review and audit internal programs for compliance
- Keep Policies & Procedures up to date with current practices

Solutions – Resources

- Internal Resources
  - Internal 340B Program Compliance Team
  - Update Policies & Procedures
- External Resources
  - Public Sources (e.g., 340B Health, 340B Report, etc.)
  - Government (e.g., HRSA, 340B Prime Vendor Program, etc.)
- Legal Consultative Services
  - Third party expert consultants (e.g., law firms, consultants, etc.)

Assessment Question #1

Manufacturer contract pharmacy restrictions & the requirements that each covered entity must abide by in order to gain 340B pricing access are the same for ALL manufacturers.

A. True

B. False

Assessment Question #1: Correct Response

Manufacturer contract pharmacy restrictions & the requirements that each covered entity must abide by in order to gain 340B pricing access are the same for ALL manufacturers.

A. True

B. <u>False</u>

Assessment Question #2

The Genesis HealthCare case has brought attention to HRSA's interpretation of the:

A. 340C program
B. Patient definition
C. Internal drug distribution model

Assessment Question #2: Correct Response

The Genesis HealthCare case has brought attention to HRSA's interpretation of the:

A. 340C program

B. Patient definition

C. Internal drug distribution model

Assessment Question #3

Which of the following resources may a covered entity utilized in order to help mitigate escalating issues within the 340B space?

1. External 340B legal resources
2. Internal compliance team
3. 340B consultative services
4. All of the above

Assessment Question #3: Correct Response

Which of the following resources may a covered entity utilize in order to help mitigate escalating issues within the 340B space?

1. External 340B legal resources
2. Internal compliance team
3. 340B consultative services
4. **All of the above**

References

- Government Accountability Office: https://www.gao.gov/assets/gao-21-107.pdf
- Health Resources and Services Administration: https://www.hrsa.gov/opa/updates/2021-340b-covered-entity-purchases
- 340B Patient Definition: https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf
- *Genesis HealthCare v. Becerra*: https://www.ca4.uscourts.gov/opinions/201701.P.pdf
- Inflation Reduction Act of 2022: https://www.irs.gov/inflation-reduction-act-of-2022
- 340B Statute: https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf
- 59 Fed. Reg. 47884 (September 19, 1994): https://www.hrsa.gov/sites/default/files/hrsa/opa/outpatient-hospital-facilities.pdf
- October 2023 Notice: https://www.govinfo.gov/content/pkg/FR-2023-10-27/pdf/2023-23702.pdf
- 75 Fed. Reg. 10272 (March 5, 2010): https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf
- 340B Statute: https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf
- National Association of Community Health Centers: https://www.nachc.org/wp-content/uploads/2023/11/340b-restrictions-summary-chart1_.pdf
- 340B Litigation Tracker: https://www.mcdermottplus.com/340b-litigation-tracker-registration/
- HELP Committee: https://www.help.senate.gov/ranking/newsroom/press/ranking-member-cassidy-seeks-information-from-major-contract-pharmacies-as-part-of-ongoing-340b-investigation
- Patient Definition: https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf
- Hospital OPPS Final Rule: https://www.govinfo.gov/content/pkg/FR-2023-07-31/pdf/2023-14768.pdf
- Baptist Health v. Humana Docket: https://dockets.justia.com/docket/alabama/almdce/2:2024cv00077/82283
- Centers for Medicare and Medicaid Services Bulletin: https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf
- Memorial Care Settlement: https://www.justice.gov/usao-cdca/pr/oc-based-health-care-organization-agrees-pay-over-315-million-settle-claims-it
- Pomona Valley Medical Center Settlement: https://www.justice.gov/usao-cdca/pr/pomona-hospital-agrees-pay-more-2-million-after-self-reporting-overbilling-medi-cal
- SUSTAIN 340B Act Discussion Draft: https://www.thune.senate.gov/public/_cache/files/5e99f492-7a5e-428d-a25e-f4722cfd4b38/26132C0D072A3EF9EB32FB58CFEF5819.340b-discussion-draft-explanatory-document-and-subsequent-rfi.pdf
- 340B Access Act: https://www.nachc.org/wp-content/uploads/2024/05/340B-ACCESS-Act-Text.pdf

HEALTHTRUST
UNIVERSITY CONFERENCE

CELEBRATING 25 TWENTY-FIVE YEARS

Thank You

Steven Schnelle, JD
Partner, McDermott Will & Emery LLP
sschnelle@mwe.com