

Stark Law Overhaul

An In-Depth Series on CMS's New Final Rule

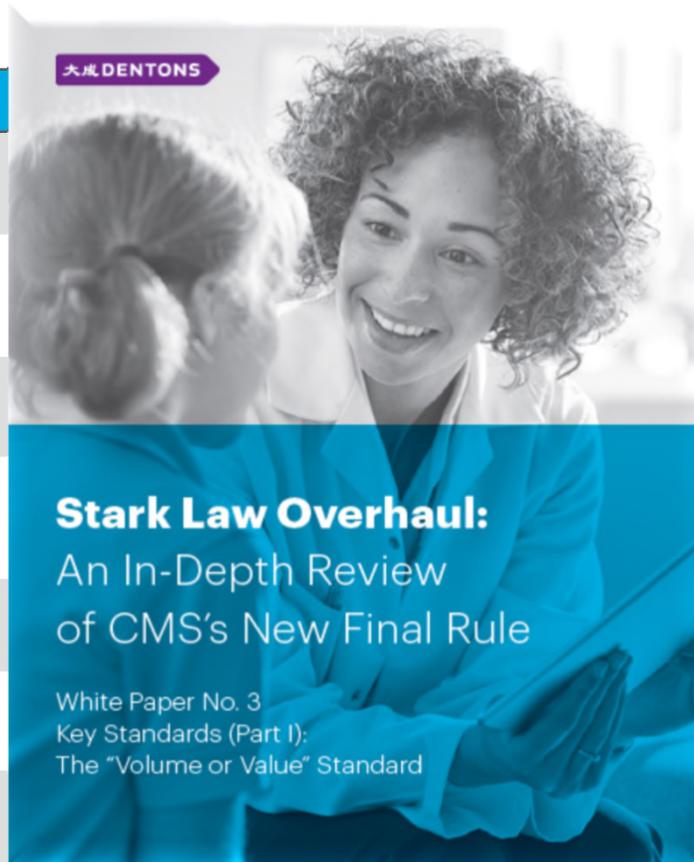


Webinar 3

Key Standards (Part I): The “Volume or Value” Standard

Stark Law Overhaul Series

Date	Topic
March 18	Rolling Up Our Sleeves: A Stark Law Refresher (and Clearing the Brush)
April 1	Separating the Wheat From the Chaff: Technical Requirements, Low-Dollar Violations, and Payment Discrepancies
April 15	Key Standards (Part I): The 'Volume or Value' Standard
April 29	Key Standards (Part II): The 'Fair Market Value' and 'Commercial Reasonableness' Standards, and Indirect Compensation Arrangements
May 13	New Wine in Old Bottles: Providing Greater Flexibility Under Existing Exceptions
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Stark Law Overhaul:
An In-Depth Review
of CMS's New Final Rule

White Paper No. 3
Key Standards (Part I):
The "Volume or Value" Standard

Agenda

- Background
- Two Key Terms
- Volume/Value Standard
- Unit-Based Special Rules
- Required Referrals
- Personally Performed Services
- Q&A

Background

Volume/Value Standard Overview

- As we've discussed (webinar 1), analyzing an arrangement under the Stark Law is a three-step process.
 - Do we have a physician/IFM who has a **financial relationship** with an entity that furnishes DHS (DHS Entity)?
 - If so, does the physician make **referrals** to the DHS Entity for the furnishing of DHS covered by Medicare?
 - If so, is there an **exception** that applies to the financial relationship or DHS at issue?
- Embedded throughout the Stark Law—including in each of these three steps—is some version of what commonly is referred to as the “volume or value standard” (**Volume/Value Standard**).

Does the compensation provided for under the arrangement at issue take into account the volume or value of the physician's referrals to, or other business generated for, the DHS Entity?

- Volume/Value Standard is subject to several important variations.

Four Functions of Volume/Value Standard

- **Indirect Compensation Arrangement (ICA) Definition**

- Version of Volume/Value Standard included in second prong of ICA Definition, 42 C.F.R. § 411.354(c)(ii) (will be addressed in fourth white paper and webinar).

- **Compensation Arrangement Exceptions**

- Versions of Volume/Value Standard included in over 20 Stark Law exceptions.

- **Unit-Based Volume/Value Standard**

- Version of Volume/Value Standard included in “unit-based special rules on compensation,” 42 C.F.R. § 411.354(d)(ii)-(iii).

- **Group Practices**

- Version of Volume/Value Standard included in special rules regarding how a “group practice” may compensate its members and/or other physicians in the group practice, 42 C.F.R. § 411.352(i) (will be addressed in fifth white paper and webinar).

Two Key Terms

Key Terms: “Referral”

- Definition codified at 42 U.S.C. § 1395nn(h)(5) and 42 C.F.R. § 411.351.
- With certain limited exceptions, the term, referral =
 - either (i) **order or request of**, or (ii) **certification (or recertification) of plan of care** that includes
 - **designated health services** (DHS)
 - covered by **Medicare**
- The term does not include:
 - Physician’s **personally performed services**,
 - Orders, requests and certifications (or recertifications) for **non-DHS**, or
 - Orders, requests and certifications (or recertifications) for **DHS not covered by Medicare**.

Key Terms: “Other Business Generated”

Other Business Generated

- Not defined in statute or regulations
- With certain limited exceptions, other business generated =
 - either (i) order or request of, or (ii) certification (or recertification) of plan of care, including
 - **any items or services** (including DHS)
 - **not covered by Medicare**

Other Business Generated (cont'd)

- Other business generated also =
 - either (i) order or request of, or (ii) certification (or recertification) of plan of care, including
 - items or services that are **covered by Medicare, but are not DHS**
- Other business generated does not include physician’s personally performed services.

Volume/Value Standard

History of Volume/Value Standard

- Prior to Proposed Rule, CMS focused principally on what **does not** (rather than on what **does**) take into account the volume or value of referrals or other business generated.

Unit-Based Special Rules

Required Referrals Special Rule

Personally Performed Services

Flat Fee Compensation

- Can a **flat fee** (i.e., fixed, aggregate compensation) take into account the volume or value of referrals or other business generated?

2001

Unclear

- At least with respect to group practice compensation, “a compensation structure does not directly take into account the volume or value of referrals if there is no **direct correlation** between the total amount of a physician’s compensation and the volume or value of the physician’s DHS referrals.”

2004

Yes

- ICA Volume/Value Standard can be triggered by “fixed, aggregate compensation” under certain circumstances—e.g., when “the fixed compensation **exceeds fair market value** for the items or services provided or is **inflated to reflect the volume or value of a physician’s referrals or other business generated.**”
- CMS’s guidance appeared to apply to Volume/Value Standard generally.

Volume/Value Special Rules - Proposed Rule (2019)

- For the first time, CMS proposes defining what **does** trigger the Volume/Value Standard.
- CMS proposes creating **two new special rules on compensation** that would offer “**bright-line**” tests for determining whether compensation takes into account the volume or value of referrals or other business generated.
- First special rule would apply to compensation *from* a **DHS Entity** *to* a **physician**.
- Second special rule would apply to compensation *from* a **physician** *to* a **DHS Entity**.
- Each special rule would include **two sub-rules**: one addressing “referrals” and the other addressing “other business generated.”

Volume/Value Special Rules - Proposed Rule

- **Unit-Based Special Rules critical to analysis.**
- If (i) conditions of the proposed special rules were met *and* (ii) compensation methodology did not satisfy requirements of the **Unit-Based Special Rules**, then compensation at issue would be considered to take into account the volume or value of referrals or other business generated.
- Proposed special rules included “narrowly-defined circumstances” under which **flat fee compensation** would be considered to take into account the volume or value or referrals or other business generated.
- Proposed special rules also **would** apply to Volume/Value Standard in prong two of ICA definition.

Volume/Value Special Rules - Final Rule (2020)

- CMS adopts two new special rules defining when compensation will be considered to take into account the volume or value of referrals or other business generated (**Volume/Value Special Rules**).

Compensation *from* DHS Entity *to* Physician

- **Referrals.** Compensation takes into account volume or value of referrals “**only if**” formula used to calculate physician’s compensation includes physician’s referrals to DHS Entity as a “**variable**,” resulting in an increase or decrease in compensation that “**positively correlates**” with number or value of physician’s referrals to DHS Entity.
- **Other Business Generated.** Same rule, replacing “referrals to” with “other business generated for.”

Compensation *from* Physician *to* DHS Entity

- **Referrals.** Compensation takes into account volume or value of referrals “**only if**” formula used to calculate physician’s compensation includes physician’s referrals to DHS Entity as a “**variable**,” resulting in an increase or decrease in compensation that “**negatively correlates**” with number or value of physician’s referrals to the DHS Entity.
- **Other Business Generated.** Same rule, replacing “referrals to” with “other business generated for.”

Volume/Value Special Rules - Application

- Hypothetical
 - Medical Practice agrees to pay Physician incentive compensation equal to 20% of a bonus pool comprised of Medical Practice's collections from defined service line that includes DHS.
- Compensation formula =
 - (.20 x [value of Physician's referrals of DHS]) +
 - (.20 x [value of other business generated by Physician]) +
 - (.20 x [value of services furnished by Medical Practice referred/generated by *other* physicians in pool])
- Volume/Value Special Rule conditions are met:
 - This is compensation *from* a DHS Entity (i.e., Medical Practice) *to* a physician.
 - Value of Physician's referrals is a **variable** in the compensation formula.
 - Value of other business generated by Physician is a **variable** in the compensation formula.
 - There is a **positive correlation** between each of these variables and the amount of Physician's incentive compensation.

Volume/Value Special Rules - Differences from Proposed Rule

- **ICA Volume/Value Standard**

- Volume/Value Special Rules do not apply to ICA Definition.

- **Flat Fee Compensation**

- CMS declined to adopt provisions from Proposed Rule that would have defined circumstances under which flat fee compensation would be considered to take into account the volume or value of referrals or other business generated.
- Given that only compensation methodologies that meet the conditions of the Volume/Value Special Rules will be considered to take into account the volume or value of referrals or other business generated, CMS appears to have decided that **flat fee compensation cannot violate the Volume/Value Standard**.

- **Unit-Based Special Rules do not apply to the analysis.**

- “If **compensation takes into account the volume or value of referrals or the volume or value of other business generated** under [the new **Volume/Value Special Rules**], that determination is final. The [**Unit-Based Special Rules**] may not be applied to then deem the compensation not to take into account the volume or value of referrals or other business generated.”

Unit-Based Special Rules

Overview

- Promulgated as part of Stark II Phase I Regulations (2001)
 - 42 C.F.R. § 411.354(d)(2) - Referrals.
 - 42 C.F.R. § 411.354(d)(3) - Other Business Generated.
- **Deeming Provision.** If Unit-Based Special Rules were satisfied, the Volume/Value Standard in the relevant compensation arrangement exception(s) was **not** violated.
- In preamble to Stark II Phase II Regulations (2004), CMS took position that Unit-Based Special Rules did not apply to Volume/Value Standard in prong two of ICA definition.
- Note.
 - Not exclusive.
 - Compensation methodology that did not fit within Unit-Based Special Rules did not necessarily violate Volume/Value Standard.

Basic Rule and Hypothetical

- Unit-based compensation methodology—e.g., \$150 per hour, \$150 per patient encounter, \$225 per imaging study—does not take into account the volume or value of referrals or other business generated if *unit of compensation* (e.g., \$225 per imaging study):
 - is **consistent with fair market value** (FMV); and
 - **does not change** during course of compensation arrangement in any manner **that takes into account the volume or value of referrals** or **other business generated**.
- Hypothetical
 - Medical Practice (owned by Physicians A and B) acquires imaging technology that is unique to its community.
 - Hospital enters into services agreement with Medical Practice, pursuant to which Hospital (i) furnishes imaging studies to its outpatient population *under arrangements*, and (ii) pays Medical Practice \$225 per imaging study.

Analysis

- By virtue of physician “stand in the shoes” provisions, arrangement gives rise to a direct compensation arrangement between each of Physician A and Physician B and Hospital, requiring reliance on an exception.
- Stark Law exception for fair market value compensation requires that compensation **not** take into account the volume or value of referrals or other business generated.
- Each time Physician A or B orders an imaging study for Hospital outpatient (i.e., makes a referral of DHS to Hospital), Hospital pays Medical Practice \$225.
- But under Unit-Based Special Rules, the arrangement would **not** violate the Volume/Value Standard, provided:
 - \$225 per study is **FMV** for the imaging study, and
 - Rate of \$225 per study **does not change** during the course of the arrangement **based on the volume or value of studies ordered** (e.g., \$225 for first 100 studies, after which Hospital will pay \$240 per study).

Final Rule

- Proposed Rule (2019) left Unit-Based Special Rules unchanged.
- Final Rule (2020) made significant changes.
 - Folded Unit-Based Special Rules into prong two of the definition of an ICA.
 - Will be addressed in fourth webinar and white paper.
 - **Retired unit-based special rules effective January 19, 2021.**
 - “[I]f compensation takes into account the volume or value of a physician’s referrals to an entity or the volume or value of other business generated by a physician for an entity under final [Volume/Value Special Rules], no special rule, including [the Unit-Based Special Rules], may be applied to reverse that determination.”
 - Unit-Based Special Rules will still apply to compensation exchanged under compensation arrangements that pre-date January 19, 2021.
 - But, they have no application for compensation exchanged from January 19, 2021 forward.

Impact - Revisit Hypothetical

- As discussed, payment of \$225 per imaging study gives rise to a direct compensation arrangement.
- Every time Physician A or Physician B orders imaging study for Hospital outpatient (i.e., makes a referral of DHS), Hospital pays Medical Practice \$225, meaning the compensation arrangement appears to take into account referrals and other business generated by each of Physician A and Physician B.
- Before the Final Rule, the parties could rely on the Unit-Based Special Rules to avoid violating the Volume/Value Standard in the relevant Stark Law exception.
- As of January 19, 2021, however, the Unit-Based Special Rules are no longer available. Thus, as of that date, **the arrangement appears to give rise to a Stark Law violation.**
- Note. No opportunity for public comment.

Required Referrals

The Question

- Health care providers typically require their physician employees or agents to refer patients to their organization.
- Managed care organizations require contracted physicians to make referrals to in-network providers, as a way to manage the overall cost of care.
- In these situations, the compensation paid to the physician is conditioned on the physician directing referrals (in the clinical sense) to certain providers.
- **Does that mean the compensation takes into account the volume or value of referrals of DHS or other business generated?**

Required Referrals Special Rule

- Before Final Rule, the answer was “yes,” but **Special Rule for Required Referrals**, 42 C.F.R. § 411.354(d)(4), created in 2001, protected this compensation.
- It acted as a **deeming** provision: If Special Rule was satisfied, the compensation was deemed not to take into account the volume or value of referrals or other business generated.
- Note.
 - Limited to employment, personal services, and managed care arrangements.
 - Applied only if the required referrals related solely to the physician’s services covered under the arrangement.

Changes Made by Final Rule

- Final Rule removes Required Referrals Special Rule from analysis of whether Volume/Value Standard is triggered.
- Due to new Volume/Value Special Rule, it is no longer the case that, without more, compensation conditioned on referrals takes into account the volume or value of referrals of DHS or other business generated.
- But the Required Referrals Special Rule is **still here**—now incorporated into relevant Stark Law **exceptions**.

Examples

- | | |
|--------------------------------------|---------------------------------------|
| • Employment | • Physician Recruitment |
| • Personal Service Arrangements | • FMV Compensation |
| • Indirect Compensation Arrangements | • Limited Remuneration to a Physician |

Personally Performed Services

Personally Performed Services Rule

- **Predicates**

- Physician's **personally performed services** (i.e., professional component (PC) services) do not give rise to a **referral** (2001 Phase I Regulations).
- Physician's **personally performed services** (i.e., PC services) do not give rise to **other business generated** (2004 Phase II Regulations).

- **Personally Performed Services Rule**

- DHS Entity may compensate physician based on personally performed services—e.g., \$80 per worked Relative Value Unit (wRVU)—without triggering Volume/Value Standard.
- **But what happens if physician's PC services are associated with one or more procedures that are DHS—e.g., when a surgeon performs surgery (PC) in a hospital (technical component or TC)?**

Hypothetical

- **Facts**

- Hospital employs Physician (an orthopedic surgeon). Base salary is \$400,000. Physician can earn bonus of \$100 for each personally achieved wRVU in excess of 10,000 wRVUs.
- Physician achieves 12,000 wRVUs and receives bonus of \$20,000 (2,000 x \$100).
- Physician achieves 80% of wRVUs in course of performing surgeries in Hospital's outpatient operating rooms.

- **Discussion**

- In preamble to the 2004 Phase II Regulations, CMS took the position that employers could pay physician-employees a bonus based on personally performed services without running afoul of the Volume/Value Standard, even if some portion of the personally performed services are inextricably linked to hospital-based procedures that constitute DHS.
- “[The] fact that corresponding hospital services are billed would not invalidate an employed physician’s personally performed work, for which the physician may be paid a productivity bonus (subject to the fair market value requirement).”

U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc. (*Tuomey*)

- Hospital affiliate employed community-based orthopedic surgeons on part-time basis, compensating them using \$/wRVU methodology. The surgeons could earn wRVUs **only** when performing procedures at Hospital.
- Thus, there was a **direct positive correlation** between the surgeons' personally performed services (i.e., surgeries) and orders for DHS (i.e., outpatient hospital services).
- Fourth Circuit concluded that compensation paid to surgeons satisfied the ICA Volume/Value Standard in the second prong of the ICA Definition.
- Court's reasoning: "The more procedures the surgeons performed at the hospital, the more facility fees [the Hospital] collected, and the more compensation the physicians received."
- But this compensation was based solely on wRVUs; what about Personally Performed Services Rule? **Fourth Circuit concluded it was not bound by CMS's regulatory interpretation.**

Personally Performed Services - Final Rule

- CMS's response to *Tuomey*?
 - “For clarity, we **reaffirm the position we took in [2004]**. [W]ith respect to employed physicians, a **productivity bonus will not take into account the volume or value of the physician’s referrals solely because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service.**”
- CMS's position not limited to employment relationships or employment bonuses but extends to all direct and indirect compensation arrangements.
 - “An association between personally performed physician services and [DHS] furnished by an entity does not convert compensation tied solely to physicians’ personal productivity into compensation that takes into account the volume or value of their referrals to or other business generated for the entity.”
- CMS *declined to codify this policy position* in Final Rule itself, contending there was no need to do so.

Q&A

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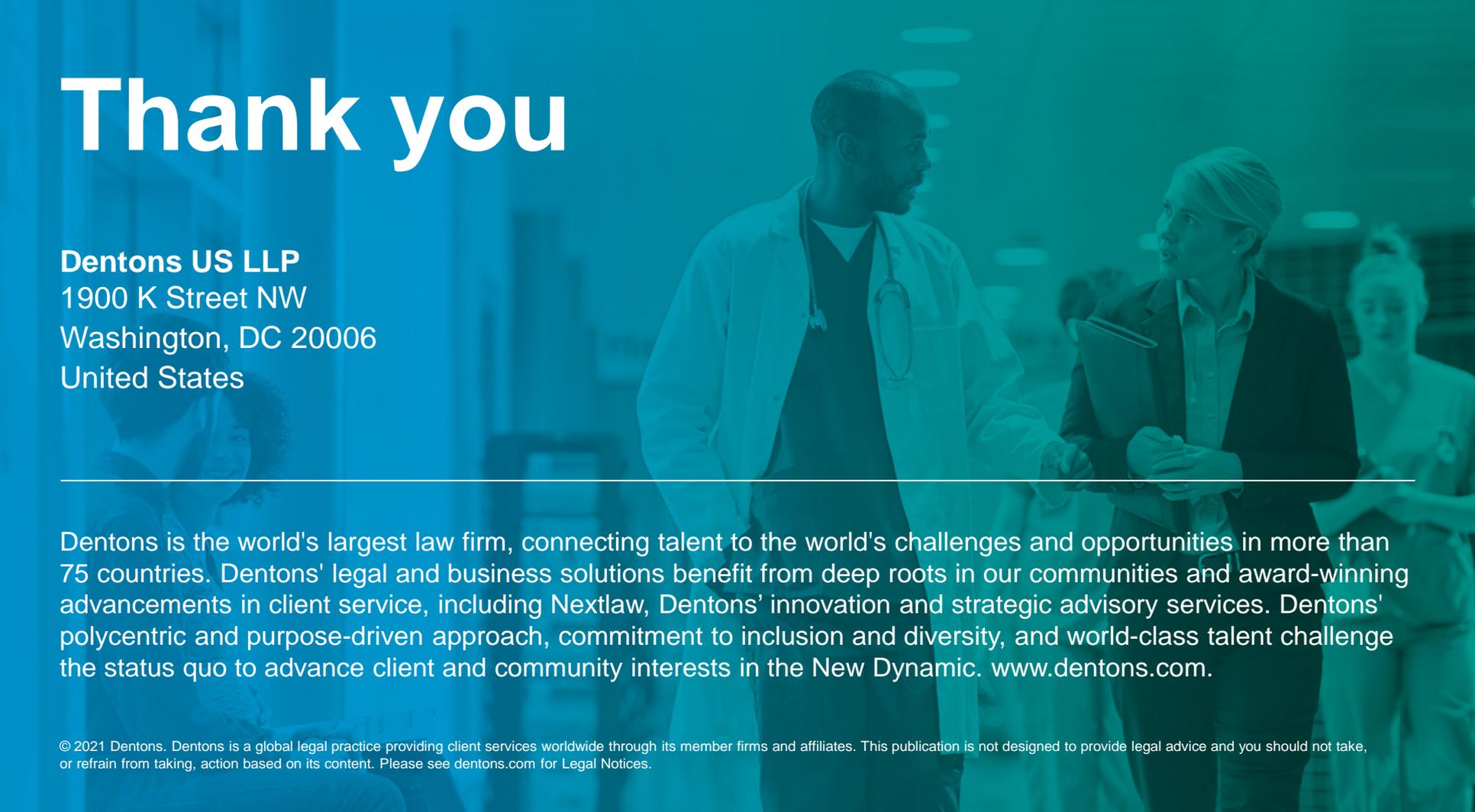
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Thank you



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