Bernie Duco joined Norton Rose Fulbright in 2014 after serving as Chief Legal Officer with the Memorial Hermann Health System. Bernie led the development of Memorial Hermann’s Medicare certified Accountable Care Organization and was the lead legal advisor for MHMD – Memorial Hermann’s clinically integrated physician group. Prior to joining Memorial Hermann, Bernie served as Senior Vice President and General Counsel for Mercy Health System in St. Louis. Having served for over 20 years as general counsel for large non-profit health systems, Bernie has broad corporate governance, transaction, and litigation management experience. Bernie received his JD from the University of Houston Law Center and his BA from Rice University. He is licensed to practice in Texas and Missouri.
Partner, Stacey Murphy practices exclusively in the health care area. She represents hospitals, multi-specialty and single specialty physician groups, post-acute care providers and other health care entities. Stacey's experience includes mergers and acquisitions, affiliations and other complex contractual arrangements among health care providers. She has been involved in structuring and negotiating joint ventures between health care providers for the formation of inpatient rehabilitation facilities and long term acute care hospitals as well as physician/hospital clinical services joint ventures, including ambulatory surgery centers and cardiac catheterization laboratories.

In addition, Stacey frequently counsels health care clients on various matters, including federal and state regulatory issues, corporate matters, tax-exempt issues, Medicare billing, reimbursement and related regulations, state licensure and general health care issues. In addition, Stacey counsels clients on corporate governance and compliance issues, including assisting health care clients in developing meaningful compliance plans.
Dan Wellington, a partner in the Washington, D.C., office, handles antitrust and trade regulation matters, including representing parties in mergers, acquisitions, and joint ventures. A substantial portion of his practice involves counseling health care providers, including hospitals, physicians, and provider networks. He has helped to form joint ventures involving high technology, health care, communications, energy, and other industries; has defended corporations, partnerships, trade associations, and others in federal and state antitrust investigations, involving allegations of price fixing, market allocation, vertical restraints, price discrimination, and advertising; and has developed compliance programs.

Mr. Wellington was an attorney in the Federal Trade Commission's Bureau of Competition for eleven years.
Overview

Clinical Integration

• Antitrust perspective

• Negotiating with private payors
  o Requirements for joint negotiation on behalf of CIN participants
  o Exclusive versus non-exclusive networks
  o Communications with payors (as part of and outside of CIN negotiations)

• Redesign of clinical practices to improve quality and efficiency
  o Advantages of early implementation of performance improvement programs and other arrangements with CIN affiliated hospitals
  o Legal and regulatory implications of programs

Recent Medicare Shared Savings Program (“MSSP”) ACO developments
Clinical Integration: The Antitrust Perspective

Defined by FTC and DOJ: an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.

- FTC and DOJ Statements of Antitrust Enforcement Policy in Health Care (1996)
Clinical Integration: The Antitrust Perspective

Attributes of clinical integration fleshed out in subsequent FTC staff advisory opinions

- Adoption of performance standards covering large percentage of services rendered
- Implementation of care enhancements that can only be achieved through collaboration
- Selectively choosing physicians who are willing and able to achieve efficiency goals
- Establishment of mechanisms, including information systems that facilitate data sharing to coordinate care and monitor individual and group performance
- Active monitoring of individual and group performance
- Education, counseling and remedial action to ensure that participants meet performance standards
- Substantial commitment of human and monetary capital
Clinical Integration: The Antitrust Perspective

Joint contracting permitted if reasonably necessary to achieve clinical integration goals

• Full participation required for success
  o consistent panels
  o in-network referrals
  o branding
  o care coordination
  o robust data base
• Prevent “free riding”
Network Negotiations and Other Communications with Private Payors

• Who is the Network negotiating for?
  o The Network, not the Network’s members, will be contracting with the Payor.
  o The Network will be negotiating for those of its members who are participating:
    - In those programs and activities through which the Network and its members are clinically integrated; and
    - In the network of providers through which the product or services offered by the Network is being provided. ("Participating Members")
What is the Network’s Negotiating Position with Private Payors?

• Meeting the CI and “Reasonably Necessary” criteria we’ve discussed, the Network may negotiate jointly on behalf of its Participating Members. In negotiating jointly, the Network may:
  o Negotiate terms that will apply to all Participating Members;
  o Collect financial and other practice information from Participating Members in order to develop acceptable contract terms; and
  o Communicate with Participating Members about the terms of the contract to be jointly negotiated.
Are the Network’s Joint Negotiations with Private Payors Exclusive or Non-Exclusive?

• “Exclusive” means that the Payor may only negotiate for a member’s services through the Network.

• “Non-Exclusive” means that the Payor may negotiate for a member’s services through the Network or it may approach the member or his or her practice group and negotiate directly.
“Exclusive” or “Non-Exclusive”? 

- The Joint Statement does not require that joint negotiations based on CI be non-exclusive.
- But every FTC advisory opinion addressing CIN’s has involved a non-exclusive network, and non-exclusivity has been viewed favorably by the FTC in its analysis of the CIN’s.
- Practical Result: A Network seeking to jointly negotiate on behalf of its members will do so on a non-exclusive basis.
Practical Result of a Non-Exclusive Network

- Payor may say “no thanks” to proposed jointly negotiated Network product and choose to negotiate with the Network’s members or their practice groups.
  - Network may not interfere with the Payor’s negotiations.
  - Network members may not collude in refusing to negotiate with the Payor.
Private Payor’s Analysis of Exclusive and Non-Exclusive Networks

• In a non-exclusive network scenario, the payor weighs the benefit provided by the Network’s jointly negotiated contract terms against the benefit the Payor can obtain by negotiating individually with the Network’s members.

• In contrast, in an exclusive network, the payor weighs the benefit provided by the Network’s jointly negotiated contract terms against the lost benefit of not having access to the Network’s members.
Network Relations with its Members

Two Common Approaches Regarding Contracting Authority

• In the Network participation agreement, the member gives the Network authority to negotiate CI-based contracts on his or her behalf.

• Under a process provided for in the Network participation agreement, the member is allowed to opt-in to participate in a CI contract prior to the Network approaching the Payor based on a range of terms provided to the member by the Network.

• Under both approaches, it is important that the Network have a good sense of what terms its members will accept before approaching the Payor.
Communicating With Private Payors Outside of Negotiations

• To attempt joint negotiations with private payors before a Network is clinically integrated can create significant anti-trust risk.

• But, early communications with Payors can be beneficial in the Network’s clinical integration development.

Recommended Approach:

• After the Network has developed its CI infrastructure and can demonstrate its objective of operating a clinically integrated network, it can initiate discussions with payors (i) to educate them about the Network and its objectives and (ii) to learn what CI programs are of interest to Payors.

• Payors often have experience in other markets and may be able to provide valuable insight in what it wants to see from the Network.

• It should be made clear to the Payors in writing that (i) these are not joint negotiations and only exploratory discussions, (ii) the discussions may be discontinued at any time, and (iii) the Payor is free to continue to negotiate with the Network’s members individually.
Performance Improvement Programs

• Engaging Physicians
  o “Priming the pump” with simple focused financial arrangements

• Creating CIN infrastructure
  o Opportunity for hospital members to invest in creation of CIN infrastructure to collect and measure clinical data and to organize and manage CIN members

• Redesigning clinical practices to improve quality and efficiency
  o Implementation of clinical best practice guidelines
  o Opportunity to reward appropriate clinical behavior in a simple straightforward manner
  o Practice competencies in preparation for value based contracting with private payors

• Future goal = payor recognition of CIN as clinically integrated
Legal and Regulatory Issues

Anti-Kickback Statute (“AKS”)

• Generally prohibits payment/receipt of payment for referring or recommending any item/service for which payment may be made under a federal or state health care program
• A kickback may exist if *one purpose* of the payment is to induce referrals, regardless of any other, legitimate reason for such payment

Physician Self-Referral Law (“Stark Law”)

• Prohibits physicians from referring patients for certain designated health services to an entity with which the physician (or a member of a physician’s immediate family) has a financial relationship (ownership or compensation), unless an exception applies
• Most exceptions require that the compensation be consistent with fair market value and not take into account volume or value of referrals or other business generated between the parties
• Also prohibits an entity from presenting/causing to be presented a bill or claim to anyone for DHS furnished as a result of a prohibited referral

Civil Monetary Penalties (“CMP”) Law – Beneficiary Inducement

• Prohibits any person from offering/transferring “remuneration” to any Medicare/State healthcare program beneficiary that the person knows/should know is likely to influence such beneficiary to order/receive any item/service from a particular provider/practitioner/supplier
• “Remuneration” includes waiver of any part of coinsurance/deductible amounts, and transfer of items/services for free or for other than fair market value
Legal and Regulatory Issues

Civil Monetary Penalties (“CMP”) Law – Gainsharing

• April 2015 liberalization affords some additional flexibility to historically-rigid statute
• Gainsharing CMP Statute now only prohibits payments made by hospitals to physicians to limit *medically* necessary items or services provided to physicians’ patients who are Medicare or Medicaid beneficiaries
• Gainsharing CMP rulemaking is anticipated – November 2015; warrants monitoring as to whether it will provide further insight into the application of the recent amendment
• Certain elements of 2008 Stark Law proposed exception for P4P/gainsharing arrangements may be instructive in structuring arrangements
  o Arrangement must be supported by credible medical evidence
  o Arrangement must incorporate quality metrics specified by the CMS’ Specifications for National Hospital Quality Measures or another metric deemed appropriate by CMS
• July 15, 2015 Stark proposed rule solicits comments regarding
  o Need for new exceptions to support shared savings or “gainsharing” arrangements
  o Should certain entities considered to provide high-value care be permitted to compensate physicians in ways that other entities may not? For example, should hospitals that meet quality and value metrics under the Medicare value based purchasing program be allowed to pay compensation from designated health services revenues to physicians who help the hospital meet those metrics?
Legal and Regulatory Issues

Other applicable laws

• Tax-exempt considerations
• HIPAA privacy & security
• State Laws
  o Business of insurance and any willing provider laws
  o Antitrust laws
  o Medicaid and insurance fraud and abuse provisions
  o Peer review
  o Privacy and confidentiality
<table>
<thead>
<tr>
<th>Process Measure</th>
<th>Metric Description</th>
<th>Target</th>
<th>Incentive</th>
<th>Documentation</th>
<th>Type</th>
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<tbody>
<tr>
<td>P1</td>
<td>Initial embedding &amp; utilization of Network care coordinators according to Network policies and procedures</td>
<td>&lt;90 days after joining Network</td>
<td>$1,000</td>
<td>Care coordination tracking form</td>
<td>One-Time</td>
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<tr>
<td>P2</td>
<td>Install Network Approved EMR</td>
<td>&lt;6 months after joining Network</td>
<td>$2,000</td>
<td>Signed Agreement</td>
<td>One-Time</td>
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<tr>
<td>P3</td>
<td>Link to Network CDR</td>
<td>&lt;6 months after joining Network</td>
<td>$2,000</td>
<td>CDR Reports</td>
<td>One-Time</td>
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<tr>
<td>P4</td>
<td>Achieve NCQA PCMH certification</td>
<td>Begin application in first 3 months of joining Network Approval &lt;12 months after initiation of application</td>
<td>$2,000</td>
<td>Level 1 or higher NCQA Certificate</td>
<td>One-Time</td>
</tr>
<tr>
<td>P5</td>
<td>Ongoing embedding &amp; utilization of Network care coordinators according to Network policies and procedures</td>
<td>By month four of program participation</td>
<td>$1,000</td>
<td>Activity tracked in Network IS System</td>
<td>Recurring</td>
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<tr>
<td>P6</td>
<td>Participate in assigned Pod meetings</td>
<td>≥75% meetings</td>
<td>$2,000</td>
<td>Pod Attendance</td>
<td>Recurring</td>
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<tr>
<td>P7</td>
<td>Utilization of CDR Point-Of-Care tool according to Network P&amp;P</td>
<td>75% patients in 6 months</td>
<td>$3,000</td>
<td>Practice P&amp;P &amp; CDR Tracking</td>
<td>Recurring</td>
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<tr>
<td>P8</td>
<td>Use HealthPost for specialty referrals and daily maintain schedule availability</td>
<td>&lt;90 days after joining Network</td>
<td>$2,000</td>
<td>HP Reports</td>
<td>Recurring</td>
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<tr>
<td>P9</td>
<td>Discrete EMR documentation for Network quality reporting</td>
<td>50%=$1,000; 75%=$2,000; 100%=$2,500</td>
<td>$2,500</td>
<td>CDR Reports</td>
<td>Recurring</td>
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<tr>
<td>P10</td>
<td>Network directed CME courses</td>
<td>5/year</td>
<td>$400 per</td>
<td>CME Certificate</td>
<td>Recurring</td>
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<tr>
<td>P11</td>
<td>Participation in &gt; 1 telemedicine service</td>
<td>&gt;1 (retina, derm, etc.)</td>
<td>$1,000</td>
<td>Epic Report</td>
<td>Recurring</td>
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<tr>
<td>P12</td>
<td>After hours clinic access</td>
<td>&gt;40 days/year</td>
<td>$1,000</td>
<td>Office Hours</td>
<td>Recurring</td>
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</table>
MSSP ACO Waivers

- **Pre-Participation Waiver**
  - **Waives:** Stark Law, Federal Anti-kickback Statute (AKS), Gainsharing CMP with respect to start-up arrangements that pre-date an ACO’s participation agreement with CMS

- **Participation Waiver**
  - **Waives:** Stark, AKS, Gainsharing CMP with respect to any arrangement of an ACO, one or more of its ACO participants or its ACO providers/suppliers, or a combination thereof

- **Shared Savings Distribution Waiver**
  - **Waives:** Stark, AKS, Gainsharing CMP with respect to distributions or use of shared savings earned by an ACO

- **Physician Self-Referral Law Waiver**
  - **Waives:** AKS and Gainsharing CMP with respect to any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers that implicates the Physician Self-Referral Law

- **Waiver for Patient Incentives**
  - **Waives:** Beneficiary Inducements CMP and AKS with respect to items or services provided by an ACO, its ACO participants, or its ACO providers/suppliers to Medicare fee-for-service beneficiaries for free or below fair-market-value
MSSP ACO Waiver Requirements

• ACO must be in good standing under its MSSP agreement and continue to meet MSSP organizational requirements or be a party acting with the good faith intent to develop an ACO

• ACO board must make a bona fide determination that the arrangement in question is reasonably related to one or more of the purposes of the MSSP:
  o Promoting accountability for the quality, cost, and overall care for a Medicare patient population
  o Managing and coordinating care for Medicare fee-for-service beneficiaries
  o Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare fee-for-service beneficiaries

• Arrangement and authorization by the ACO board must be documented

• The description of the arrangement must be publicly disclosed
MSSP ACO Matters

• Facilitating CIN Objectives
  o FTC/DOJ Final Policy Statement – October 28, 2011
    – “Deemed” CI Status
    – Potential for an Exclusive, “Single Signature” CIN Contract

• CMS/OIG Waivers
State of the Medicare Shared Savings Program (Late 2015)

- 330 MSSP ACOs in operation
- In 2014, 92 ACOs held spending a combined $806 million below their targets and earned performance payments of more than $341 million
- The MSSP continues to receive strong interest from both new applicants and existing ACOs seeking to continue participation in the program
- CMS values the MSSP as part of a larger effort to link a significant portion of physician and hospital reimbursement to the quality and efficiency of care provided
ACOs with Pending Applications: What's Next

- Design care pathways to more effectively manage high-cost populations
- Build up infrastructure to monitor quality data
- Begin deploying initiatives under the MSSP waivers
# Summary of Finalized Tracks 1-3

<table>
<thead>
<tr>
<th></th>
<th>Track 1</th>
<th>Track 2</th>
<th>Track 3</th>
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</thead>
<tbody>
<tr>
<td><strong>Assignment Methodology</strong></td>
<td>Preliminary prospective, with retrospective reconciliation</td>
<td>Preliminary prospective, with retrospective reconciliation</td>
<td>Prospective, with limited retrospective reconciliation</td>
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<td><strong>Sharing Rate</strong></td>
<td>Up to 50%</td>
<td>Up to 60%</td>
<td>Up to 75%</td>
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<tr>
<td><strong>Minimum Savings Rate</strong></td>
<td>2.0 - 3.9% depending on number of assigned beneficiaries</td>
<td>Several options available to ACO (in each case symmetrical to Minimum Loss Rate)</td>
<td>Same as Track 2</td>
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<tr>
<td><strong>Performance Payment Limit</strong></td>
<td>10%</td>
<td>15%</td>
<td>20%</td>
</tr>
<tr>
<td><strong>Loss Rate</strong></td>
<td>N/A</td>
<td>40 - 60%</td>
<td>40 - 75%</td>
</tr>
<tr>
<td><strong>Minimum Loss Rate</strong></td>
<td>N/A</td>
<td>Several options available to ACO (in each case symmetrical to Minimum Savings Rate)</td>
<td>Same as Track 2</td>
</tr>
<tr>
<td><strong>Loss Sharing Limit</strong></td>
<td>N/A</td>
<td>5 - 10% (phased in)</td>
<td>15%</td>
</tr>
</tbody>
</table>
Organizations Considering Applying for 2017

• Use of Pre-Participation Waiver available now: offers a broad waiver of the Stark Law, Anti-Kickback Statute, and Gainsharing CMP

• Procedural requirements
  o The arrangement is undertaken by a party or parties acting with the good faith intent to develop an ACO
  o The parties developing the ACO must be taking diligent steps to develop an ACO that would be eligible for a participation agreement
  o The ACO's governing body has made a bona fide determination that the arrangement is reasonably related to the purposes of the MSSP
  o The arrangement, its authorization by the governing body, and the diligent steps to develop the ACO are documented. The documentation must identify at least the following:
    • A description of the arrangement, including all parties to the arrangement and the financial or economic terms of the arrangement
    • The date and manner of the governing body's authorization of the arrangement, including the Board's “reasonably related” determination
    • A description of the diligent steps taken to develop an ACO
  o The description of the arrangement is publicly disclosed (such disclosure shall not include the financial or economic terms)

• Seek legal advice: pros/cons regarding forming the ACO as the same legal entity as a CIN entity

• Notice of Intent typically due preceding May
Standing of Related Agency Pronouncements

• OIG's Interim Final Rule re: MSSP Waivers (of Fraud & Abuse laws) technically set to expire November 2, 2015
  o In the absence of a final rule, most likely would be extended, as it has been before, but should be monitored closely
• FTC/DOJ Final Antitrust Enforcement Policy Statement and IRS Fact Sheet dated November 2, 2011 are still in effect
  o Unlike the OIG's Interim Final Rule re: MSSP Waivers, this guidance would not expire unless affirmatively supplanted
Appendices

• MSSP CMS/OIG Waiver Requirements
1. Pre-Participation Waiver Requirements

- The arrangement is undertaken by a party or parties acting with the good faith intent to develop an ACO
- The parties developing the ACO must be taking diligent steps to develop an ACO that would be eligible for a participation agreement
- The ACO's governing body has made a bona fide determination that the arrangement is reasonably related to the purposes of the MSSP
- The arrangement, its authorization by the governing body, and the diligent steps to develop the ACO are documented. The documentation must identify at least the following:
  - A description of the arrangement, including all parties to the arrangement and the financial or economic terms of the arrangement
  - The date and manner of the governing body's authorization of the arrangement, including the Board’s “reasonably related” determination
  - A description of the diligent steps taken to develop an ACO
- The description of the arrangement is publicly disclosed (such disclosure shall not include the financial or economic terms)
- If an ACO does not submit an application for a participation agreement for the target year, the ACO must submit a statement describing the reasons it was unable to submit an application
2. Participation Waiver Requirements

- The ACO has entered into a participation agreement and remains in good standing.
- The ACO meets the requirements of the regulations relating to governance, leadership, and management.
- The ACO's governing body has made and duly authorized a bona fide determination that the arrangement is reasonably related to the purposes of the MSSP.
- Both the arrangement and its authorization by the ACO’s governing body are documented. The documentation must identify at least the following:
  - A description of the arrangement, including all parties to the arrangement, the purposes of the arrangement, the items, services, facilities and/or goods covered by the arrangement and the financial or economic terms of the arrangement.
  - The date and manner of the governing body's authorization of the arrangement, including the ACO governing body’s determination that the arrangement is reasonably related to the purposes of the MSSP.
- The description of the arrangement is publicly disclosed (disclosure shall not include the financial or economic terms).
3. Shared Savings Waiver Requirements

- The ACO has entered into a participation agreement and remains in good standing under its participation agreement with CMS
- The shared savings are earned by the ACO pursuant to the MSSP
- The shared savings are earned by the ACO during the term of its participation agreement, even if the actual distribution or use of the shared savings occurs after the expiration of that agreement
- The shared savings are:
  - Distributed to or among the ACO’s ACO participants, its ACO providers/suppliers, or individuals and entities that were its ACO participants or its ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or
  - Used for activities that are reasonably related to the purposes of the MSSP
- With respect to the waiver Gainsharing CMP, payments of shared savings distributions made directly or indirectly from a hospital to a physician are not made knowingly to induce the physician to reduce or limit medically necessary items or services to patients under the direct care of the physician.
4. Physician Self-Referral Waiver Requirements

- The ACO has entered into a participation agreement and remains in good standing under its participation agreement with CMS
- The financial relationship is reasonably related to the purposes of the MSSP
- The financial relationship fully complies with a Stark Law exception
5. Patient Incentive Waiver Requirements

- The ACO has entered into a participation agreement with CMS and remains in good standing.
- There is a reasonable connection between the items or services and the medical care of the beneficiary.
- The items or services are *in-kind* and:
  - Are preventive care items or services; or
  - Advance one or more of the following clinical goals:
    - Adherence to a treatment regime.
    - Adherence to a drug regime.
    - Adherence to a follow-up care plan.
    - Management of a chronic disease or condition.
- Examples of permitted incentives include:
  - Blood pressure cuffs for hypertensive patients
  - Smoking cessation treatment
  - Free home visits to coordinate in-home care during a post-surgical patient’s recovery period
- Excludes financial incentives. For example:
  - Waiving copayments or deductibles
  - Sporting or entertainment event tickets
  - Jewelry, household items, beauty products, gift certificates for non-health care related retail items
- Prohibition on providing gifts or other remuneration to Medicare beneficiaries as inducements for joining/remaining in the ACO or seeing providers in the ACO.
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• We have applied for one hour of California, Texas, Virginia CLE and New York non-transitional CLE credit. Newly admitted New York attorneys may not receive non-transitional CLE credit. For attendees outside of these states, we will supply a certificate of attendance which may be used to apply for CLE credit in the applicable bar or other accrediting agencies.

• Norton Rose Fulbright will supply a certificate of attendance to all participants who:
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  2. Complete our online evaluation that we will send to you by email within a day after the event has taken place
Continuing education information

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• Please direct any questions regarding the administration of this presentation to Cristina De Los Santos at cristina.delossantos@nortonrosefulbright.com.
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