NEW TRANSPARENCY RULES SURPRISE BILLING PROTECTIONS FOR 2022

Sage Fattahian and Allison Fepelstein

September 29, 2021

Morgan Lewis

Agenda

- **Transparency in Coverage** – Final Rule
- **No Surprises Act** – Interim Final Rule (Part I)
- **Consolidated Appropriations Act, 2021** – Additional Surprise Billing and Transparency Provisions

Background

- **President Trump's "Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First"**
  - Price Disclosure Mandates
  - Surprise Medical Billing Policy Option
- **Transparency in Coverage – Final Rule**
- **Consolidated Appropriations Act, 2020**
  - Included:
    - Surprise Medical Billing (Division BB, Title I – No Surprises Act)
    - Transparency Provisions (Division BB, Title II – Transparency)
  - FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49
- **No Surprises Act**
  - Requirements Related to Surprise Billing; Part I – Interim Final Rule
  - Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement

  Still awaiting formal guidance on the Independent Dispute Resolution (IDR) process, consumer protections, transparency, and price comparison tool

Transparency in Coverage – Final Rule

Morgan Lewis

Final Rule Overview

- Published November 12, 2020
- Implements ACA Section 1311(e)(3) and PHSA Section 2715A, which requires group health plans and health insurance issuers offering group or individual health insurance coverage to:
  - provide information to enrollees on the amount of cost-sharing for a specific item or service
  - disclose, to the federal government and the state insurance commissioner, certain enrollee information such as claims payment policies and practices and enrollee rights
- Phased in effective dates
  - Additional delays under ACA/CAA FAQ Part 49

Final Rule Overview

- Establishes two requirements for the disclosure of cost-sharing and pricing information:
  - Public disclosure requirements via machine-readable files
  - Required disclosures to participants and beneficiaries via an internet self-service tool
- Applicability
  - Applies to non-grandfathered health plans
  - Does NOT apply to grandfathered plans, HRAs, Health FSAs, excepted benefits, and short-term, limited-duration insurance
  - Operates in tandem with (and does not supersede or alter plan's and issuer's responsibilities under) existing federal and state laws governing data privacy, security, and accessibility (e.g., HIPAA/HITECH)

Required Cost-Sharing Disclosures to Participants

- Group health plans and health insurance issuers must provide participant-specific cost-sharing information upon the request of participants, beneficiaries, or enrollees who are enrolled in a group health plan/insurance coverage (collectively, “participants”)
- This disclosure will take the form of an **online self-service tool** that allows participants to search for certain cost-sharing information
  - Information must be accurate at the time the request is made
  - Provided free of charge without a subscription
  - “Plain language” requirement
  - Paper copies provided upon request (or disclosed over the phone or via email)
  - Seven content elements

Cost-Sharing Disclosure Contents

1. Estimated Cost-Sharing Liability

- Includes deductibles, coinsurance, copayments
- Does not include premiums, balance billing amounts charged by out-of-network providers, costs of non-covered items and services

2. Accumulated Amounts

- The amount of financial responsibility incurred by a participant at the time of request with respect to the applicable deductible or out-of-pocket limit
- includes how many visits/items/days the participant has used within a cumulative treatment limitation, regardless of any need to determine medical necessity for future visits

Cost-Sharing Disclosure Contents

3. In-Network Rates

- Comprised of negotiated rate and any underlying fee schedule rate
  - Negotiated rate must always be disclosed with cost-sharing liability estimates, even if such rate is not used to determine the reported cost-sharing liability
  - The underlying fee schedule used to determine the cost-sharing liability should also be disclosed (if different from the negotiated rate)
- Must be expressed as a dollar amount

4. Out-of-Network Allowed Amount

- The maximum amount a group health plan or health insurance issuer will pay for a covered item or service furnished by an out-of-network provider
- Alternatively, can disclose any other calculation that provides a more accurate estimate of the amount that the plan pays (e.g., UCR charge)

Cost-Sharing Disclosure Contents

5. **Items and Services List** (for bundled payment arrangements only)
   - "Bundled Payment Arrangement" defined as payment model under which a provider is paid a single payment for all covered items and services provided to a participant or beneficiary for a specific treatment or procedure
6. **Notice of Prerequisites of Coverage** (if applicable)
   - Includes concurrent review, prior authorization, and step-therapy or fail-first protocols related to covered items and services that must be satisfied before a group health plan or health insurance issuer will cover the item or service
   - Does not include medical necessity determinations generally or other forms of medical management technique

Cost-Sharing Disclosure Contents

7. Disclosure Notice

- Plain language requirement
- Must include:
  - A statement that out-of-network providers may engage in balance billing and that the estimated cost-sharing liability may not capture such additional charge (Note: provide this statement only if balance billing is permitted under state law);
  - A statement that actual charges may be different from the estimated cost-sharing liability;
  - A statement that the estimated cost-sharing liability is not a guarantee that coverage will be provided for the requested item/service;
  - A statement disclosing whether the plan counts copayment assistance or any third-party payments in calculating the participant's deductible and out-of-pocket maximum;
  - A statement that certain in-network item/service may not be subject to cost-sharing if billed as a preventive service; and
  - A statement including any other disclaimers or information that the plan/insurer deems appropriate.

Implementation Timeline

Two phases:

- With respect to 500 specific items and services identified by the Departments, the information must be available for plan years beginning on or after January 1, 2023*
- For all other items/services covered under the plan, for plan years beginning on or after January 1, 2024

**Enforcement of a largely duplicative rule under the CAA that requires plans to make available a price comparison tool (by internet website, in paper form, or telephone) for plan years beginning on or after January 1, 2022, has been delayed to align with this rule. The Departments intend to propose rulemaking requiring that the same pricing information that is available through the online tool or in paper form must also be provided over the telephone upon request.*

Public Disclosure of Pricing Information

- Plans and insurers are required to publish the following three machine-readable files to be available to the public:
  - In-network rate file
  - Out-of-network allowed amount file (with associated billed charges)
  - Prescription drug pricing file
- Must be updated monthly and provided free of charge and without any restrictions (e.g., no password protection)
- Each file must include applicable identifiers and billing codes for each coverage option (e.g., PPO, HMO, etc.) and show the required rate information in dollar amounts (not a formula).

Implementation Timeline

- The requirement to publish machine-readable files that disclose in-network rates, out-of-network allowed amounts, and billed charges was set to go into effect for plan years beginning on or after 1/1/2022, but has been delayed until 7/1/2022.
  - There is no impact on non-calendar year plans beginning on or after 7/1/2022 (such plans must post the machine-readable files in the month in which the plan year begins)
- The requirement to publish machine-readable files relating to prescription drug pricing was set go into effect for plan years beginning on or after 1/1/2022, but has been delayed indefinitely (pending further rulemaking)
  - This delay is, in part, due to a No Surprises Act reporting requirement that implicated the same prescription drug pricing information. Enforcement of that requirement has also been delayed (pending the issuance of regulations or further guidance). However, the Departments indicated that plans should work towards a 12/27/2022 compliance deadline.

No Surprises Act – Interim Final Rule (Part I)

The No Surprises Act

- Prohibits surprise medical billing for all out-of-network (OON) emergency services, air ambulance services, and certain OON services provided at in-network facilities
- Applies to group health plans and issuers, including self-insured group health plans and grandfathered plans
  - Does not apply to excepted benefit plans, retiree-only plans, account based plans (e.g., HRAs) or short-term, limited duration insurance
- Amends the Employee Retirement Income Security Act (ERISA), the Public Health Service Act (PHSA), and the Internal Revenue Code (Code)
  - Additional conforming PHSA provisions for providers
  - Special related amendments under the Code related to HDHP/HSAs
- Generally effective January 1, 2022
  - For certain provisions, “good faith compliance” until more formal guidance is released

What is "Surprise Medical Billing"?

"A surprise medical bill is an unexpected bill from a health care provider or facility that occurs when a covered person receives medical services from a provider or facility that, usually unknown to the participant, beneficiary, or enrollee, is a nonparticipating provider or facility with respect to the individual's coverage."

86 Fed. Reg. 36872, 36874 (July 13, 2021)

What is “Surprise Medical Billing”?

- Includes:
  - Balance billed amounts (i.e., the difference between the actual amount billed by an OON provider/facility and the allowed amount the plan/issuer will pay)
  - OON cost-sharing (e.g., copayments, coinsurance)
  - OON deductibles and out-of-pocket maximums
  - Additional fees and expenses charged by the OON provider/facility

No Surprises Act IFR

- The No Surprises Act did not go so far as to prohibit all surprise billing practices. The Interim Final Rule (IFR) focuses on three situations where patients do not have any meaningful choice of provider and are therefore most vulnerable:
  - Emergency services, when patients are typically rushed to the nearest hospital without regard to whether that hospital is in network
  - Nonemergency services, when patients are at a participating hospital or other facility but receive care from an out-of-network provider (typically ancillary providers like anesthesiologists)
  - Air ambulance services furnished by nonparticipating providers (which patients rarely get to select)

Coverage of Emergency Services

- Replaces similar Affordable Care Act provisions effective January 1, 2022
- Requires plans that cover “emergency services” do so:
  - without any prior authorization determination (including when the emergency services are provided out of network);
  - without regard to whether the provider or facility is a participating provider or participating emergency facility;
  - without limiting what constitutes an “emergency medical condition” solely on the basis of diagnosis codes (i.e., applying the prudent layperson standard before the initial denial); and
  - without regard to any other term or condition of the plan or coverage other than the exclusion or coordination of benefits or a permitted affiliation or waiting period (as permitted under ERISA, PHSA, or the Internal Revenue Code) or other cost-sharing requirements.

What is an "Emergency Service"

- Much broader than the Affordable Care Act definition which is based off of the Emergency Medical Treatment and Labor Act (EMTALA) examination and stabilization rules
  - Includes independent freestanding emergency departments
  - Includes covered items and services that are furnished by an OON provider or OON emergency facility:
    - AFTER the participant is stabilized and as part of outpatient observation or an inpatient or outpatient stay; and
    - regardless of the department of the hospital in which such items or services are furnished
  - Prudent layperson standard
    - a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in serious injury or harm to the individual.

Out-of-Network Cost-Sharing

- Cost-sharing payments for out-of-network (OON) emergency services:
  - must be counted toward any in-network (IN) deductible or out-of-pocket maximums
  - cannot be greater than IN amounts
  - calculation based on the "recognized amount"
- "Recognized Amount" – one of the following:
  - An applicable All-Payer Model Agreement (i.e., MD and VT)
  - If there is no such applicable All-Payer Model Agreement, then specified state law
  - If there no applicable All-Payer Model Agreement or specified state law, then the lesser of:
    - the amount billed by the provider or facility and
    - the median of the contracted rates of the plan or issuer for the item or service in the geographic region (i.e., the QPA)

Balance billing is not permitted!

Air Ambulance Services

- Similar to the OON emergency services rules (e.g., balance billing not permitted)
- Applicable to plans that have a network of participating providers and provide coverage for air ambulance services, even if those air ambulance providers are all OON
- Ground ambulances EXCLUDED
- Two-year reporting requirement for air ambulance providers, plans, and issuers
  - Self-insured plans would report to the DOL
  - Proposed that 2022 calendar year data will be due by March 31, 2023, and 2023 data by March 30, 2024

Nonemergency Services Provided by OON Providers at IN Facilities

- Cost-sharing for OON providers performing covered nonemergency services at IN facilities:
  - must be counted toward any IN deductible or out-of-pocket maximums
  - cannot be greater than IN amounts
  - calculation based on the "recognized amount"
- Balance billing generally not permitted
- **Exception for participants who provide informed consent**

Notice and Consent

- HHS Model Notice must generally be provided 72 hours in advance
- Narrow exception
  - Participant must be in a condition to provide informed consent
  - Cannot be used for items or services furnished as a result of an unforeseen, urgent medical need that arises contemporaneously
  - Cannot be used for specified ancillary services
- **OON providers that give proper notice and receive consent cannot later submit to the IDR process**

Pre-IDR: Open Negotiation (Overview)

- The plan must either deny the claim or determine that the claim is covered and make an "initial payment" directly to the OON provider/facility within 30 days after receiving a "clean claim"
  - Clock doesn't start ticking until the "clean claim" is received
- Once the provider/facility receives the payment or the denial, the provider/facility or plan has 30 days to initiate an open negotiation for the parties to agree to a payment amount (including any "cost-sharing")
- 30-day open negotiation period
- If the open negotiation fails, the provider/facility or the plan has four days to initiate the IDR by notifying the other party and the Secretary*
  - No minimum rate required

Payment Terms and Methodology

- **"Initial Payment"**
  - No dollar amount is specified in the IFR
  - Should be "an amount that the plan or issuer reasonably intends to be payment in full based on the relevant facts and circumstances and as required under the terms of the plan or coverage"
- **Recognized Amount**
  - The cost-sharing amount that participants will be required to pay for services subject to the No Surprises Act must be equal to the recognized amount, which is one of the following (in order of priority):
    - An amount determined by an applicable All-Payer Model Agreement
      - e.g., MD, VT, PA
    - An amount determined by state law that governs both the plan and the service
      - Won't apply in most cases to self-insured plans
    - The lesser of billed charges or the Qualifying Payment Amount (QPA)

Payment Terms and Methodology

- **Qualifying Payment Amount (QPA)**
  - the *median of the contracted rates* recognized by the plan or issuer on January 31, 2019 (indexed based on CPI-U for 2019, 2020 and 2021) for the *same or similar item or service* in the same *insurance market* that is provided by a provider in the *same or similar specialty* and provided in a *geographic region* in which the item or service is furnished, increased for inflation and separately determined for different insurance markets
  - special rules apply for new plans and coverage and newly covered items and service
  - **participants cannot be billed for any additional amounts**

Payment Terms and Methodology

- **"Out-of-Network Rate"** – the total amount paid by a plan or issuer for items and services subject to these provisions, without including cost-sharing paid by participant
  - An applicable All-Payer Model Agreement
  - If there is no such applicable All-Payer Model Agreement, then state law
  - If there no applicable All-Payer Model Agreement or specified state law, then an amount that the plan/issuer and provider/facility have agreed to
  - If none of the above three conditions apply, then an amount determined by an IDR entity

IDR Elements

- What we know:
  - "Baseball style" arbitration
  - Multiple cases may be submitted together
  - 90-day "cooling off period"
  - Determination is binding upon the parties and is not subject to judicial review
    - The plan/issuer is required to pay the provider/facility within 30 days of the determination
    - The party whose offer is not chosen is responsible for paying all fees charged
- Still waiting additional Tri-Agency rulemaking on:
  - The IDR process (by December 27, 2021)
  - A process to certify (or recertify) "IDR entities" (i.e., arbitrators)

Additional Surprise Billing and Transparency Requirements

Advanced Explanation of Benefits

- Provide "Advanced Explanation of Benefits" (through mail or electronic means) that includes:
  - Good-faith estimates from the provider of the costs of services the participant is likely to receive, such as:
    - whether a provider is IN or OON, contracted rate information for the in-network provider and how individual can get information about IN providers;
    - good faith estimate from provider;
    - good faith estimate of coverage;
    - good faith estimate of cost-sharing;
    - good faith estimate of accumulated amounts; and
    - any medical management for the item or service
  - Associated disclaimers, like the model notice noted above
  - Due within 1 business day after the date the good faith estimate is received from provider OR within 3 business days if service scheduled at least 10 business days in advance (or a request is made by participant or beneficiary) after the date the good faith estimate is received from the provider
  - *Delayed indefinitely (pending further guidance)*

Broker Disclosure of Compensation

- CAA Title II of Division BB, Section 202(a)
  - Health benefit brokers and consultants will now be required to disclose to plan sponsors a description of the following:
    - The services to be performed; and
    - Their reasonably expected direct and indirect compensation for referral of brokerage or consulting services
  - Must be provided up front at the time of contracting
  - This does not apply to insurance providers or pharmacy benefit managers
  - Only applies if direct or indirect compensation will be more than $1,000
  - Effective 12/27/21 (one year after enactment of CAA)
    - No guidance yet
    - NPRM published 9/16/2021 for broker disclosures under Section 202(c) for insurers offering individual and short-term, limited-duration coverage

Additional Disclosure Requirements

- Group health plans required to post on plan's website about participants' rights under the No Surprises Act and include the notice in Advanced Explanation of Benefits tool
  - DOL issued model notice that can be used to satisfy this requirement, at https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/surprise-billing-model-notice.docx
- Offer price comparison guidance via telephone and an online cost comparison tool*
  - *Delayed until 1/1/2023*
- Include in-network and OON deductible amounts and maximum out-of-pocket costs on insurance ID cards
  - *Delayed indefinitely (pending further guidance)*
- Provide participants with up-to-date provider directories using good faith, reasonable interpretation of the rules
  - Participants who rely on incorrect information that they receive will only be liable for in-network cost-sharing amounts
  - *Delayed indefinitely (pending further guidance)*

Additional Consumer Protections

- Directs the Tri-Agencies to issue proposed regulations under the Affordable Care Act's "Provider Nondiscrimination" protections
- Extends the Affordable Care Act's external review process to adverse benefit determinations under the surprise billing provisions
- Requires that certain participants be able to receive up to 90 days of continued coverage at in-network cost-sharing rates when their providers move out of network
- Establishes a grant program to create and improve "State All Payer Claims Databases"
  - Voluntary reporting for self-insured group health plans only
  - Federal Register Notice – March 2, 2021
- Prohibits gag clauses in service agreements
  - Generally self-implementing
  - Departments will issue guidance on attestations of compliance expected

ACA Patient Protections

- Replaces the Affordable Care Act "choice of health care professional" provisions:
  - Designation of primary care provider (PCP)
  - Pediatrician PCP designation (for children)
  - Access to OB/GYN care
    - OB/GYNs treated as PCPs
    - No prior authorizations or referrals to access OB/GYNs
- Provisions largely unchanged, but will apply to grandfathered plans
- Effective January 1, 2022

Biography

Saghi (Sage) Fattahian
Chicago
+1.312.324.1744
sage.fattahian@morganlewis.com

Sage counsels clients on all aspects of health and welfare plans. She works with clients to comply with the complicated, shifting requirements under the US Internal Revenue Code, ERISA, ACA, COBRA, HIPAA, MHPAEA, GINA, and state and local laws. She assists health and welfare plans and their sponsors with daily operations and plan administration, including preparing and maintaining plan documents and related materials; reviewing and negotiating services agreements with third parties; consulting on operational issues; and assisting with claims and appeals.

Sage also consults with clients to design and implement innovative, cost savings designs, such as high-deductible health plan/health savings account (HDHP/HSA) combinations, health reimbursement arrangements (HRAs), and health flexible spending accounts (FSAs). Sage represents health and welfare plan clients facing federal agency audits and helps them to limit their liability through comprehensive legal review.

Biography

Allison J. Fepelstein
Washington, D.C.
+1.202.739.5667
allison.fepelstein@morganlewis.com

Allison advises clients on health and welfare plans, helping them stay in compliance with applicable requirements under ERISA, the Internal Revenue Code, the Affordable Care Act, COBRA, and HIPAA. She also prepares and reviews plan documents and related materials. In addition, Allison reviews and negotiates services agreements with third parties. Before joining Morgan Lewis, Allison served in the US Department of Labor's (DOL) Office of Health Plan Standards and Compliance Assistance. There she helped develop and issue regulatory, interpretive, and compliance-assistance guidance concerning group health plans under ERISA.

While at DOL, Allison spoke frequently on behalf of the agency at outreach seminars. She assisted in developing training and compliance-assistance materials related to Part 7 of ERISA. For her work implementing the Affordable Care Act, Allison received the Secretary of Labor's Exceptional Achievement Award.

Coronavirus COVID-19 Resources

We have formed a multidisciplinary **Coronavirus/COVID-19 Task Force** to help guide clients through the broad scope of legal issues brought on by this public health challenge.

To help keep you on top of developments as they unfold, we also have launched a resource page on our website at **www.morganlewis.com/topics/coronavirus-covid-19**

If you would like to receive a daily digest of all new updates to the page, please visit the resource page to **subscribe** using the purple "Stay Up to Date" button.

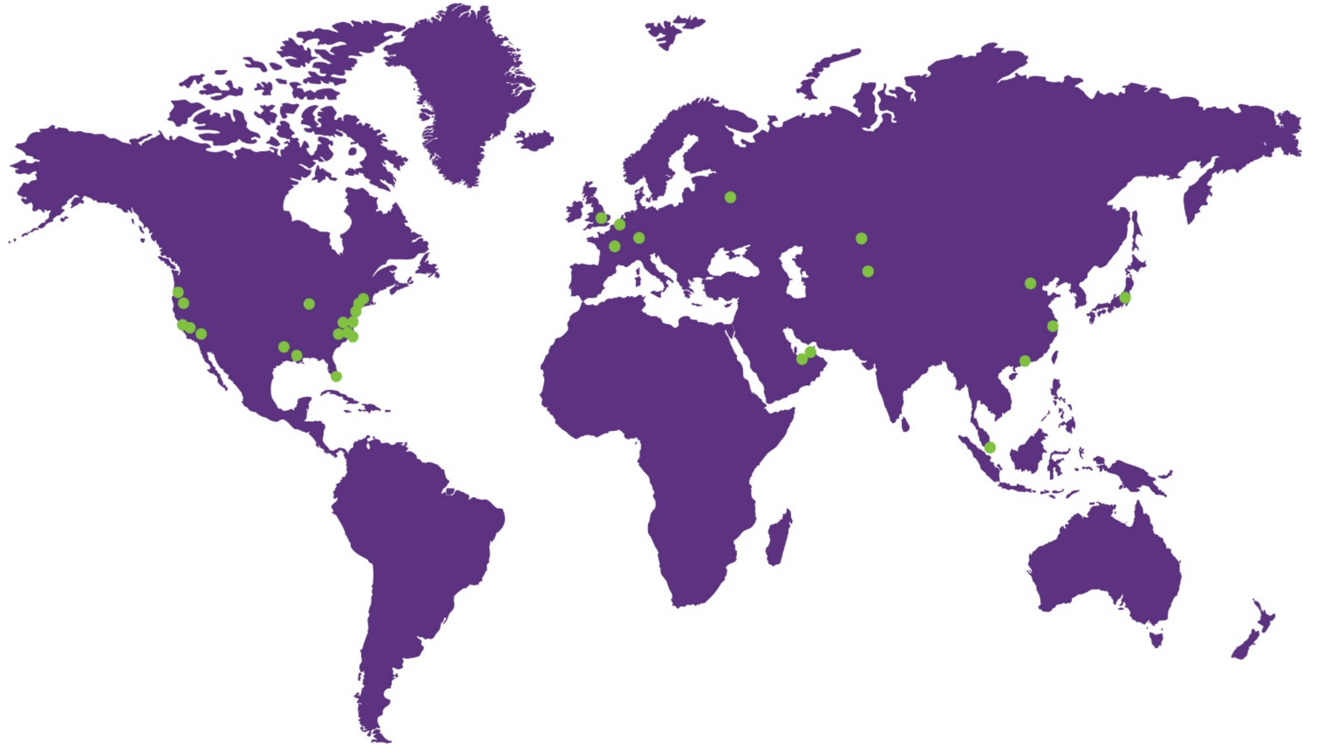
Morgan Lewis

Our Global Reach

Africa
Asia Pacific
Europe
Latin America
Middle East
North America

Our Locations

Abu Dhabi
Almaty
Beijing*
Boston
Brussels
Century City
Chicago
Dallas
Dubai
Frankfurt
Hartford
Hong Kong*
Houston
London
Los Angeles
Miami
Moscow
New York
Nur-Sultan
Orange County
Paris
Philadelphia
Pittsburgh
Princeton
San Francisco
Shanghai*
Silicon Valley
Singapore*
Tokyo
Washington, DC
Wilmington



Morgan Lewis

*Our Beijing and Shanghai offices operate as representative offices of Morgan, Lewis & Bockius LLP. In Hong Kong, Morgan, Lewis & Bockius is a separate Hong Kong general partnership registered with The Law Society of Hong Kong. Morgan Lewis Stamford LLC is a Singapore law corporation affiliated with Morgan, Lewis & Bockius LLP.

THANK YOU

© 2021 Morgan, Lewis & Bockius LLP
© 2021 Morgan Lewis Stamford LLC
© 2021 Morgan, Lewis & Bockius UK LLP

Morgan, Lewis & Bockius UK LLP is a limited liability partnership registered in England and Wales under number OC378797 and is a law firm authorised and regulated by the Solicitors Regulation Authority. The SRA authorisation number is 615176.

Our Beijing and Shanghai offices operate as representative offices of Morgan, Lewis & Bockius LLP. In Hong Kong, Morgan, Lewis & Bockius is a separate Hong Kong general partnership registered with The Law Society of Hong Kong. Morgan Lewis Stamford LLC is a Singapore law corporation affiliated with Morgan, Lewis & Bockius LLP.

This material is provided for your convenience and does not constitute legal advice or create an attorney-client relationship. Prior results do not guarantee similar outcomes. Attorney Advertising.