



## 金聖泰

Partner

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**Mr. Sung Tae Kim is a partner at Shin & Kim and leads the firm's healthcare group. His practice focuses on health insurance pricing and reimbursement in the healthcare sector, including pharmaceuticals and medical devices.**

In particular, Mr. Kim represents pharmaceutical and medical device companies in the process of health insurance listing or follow-up of new drugs, medical practices, and therapeutic materials, advising them on various matters, such as price determination, expansion of benefit standards, and response to follow-up of drug prices or therapeutic material prices. He also guides clients on the medical practice evaluation procedures for new or innovative health technologies. Mr. Kim worked as a lawyer for the Ministry of Health and Welfare for six years between 2005 and 2011, where he was in charge of an array of activities related to healthcare, including health insurance listing for drugs and therapeutic materials and administrative litigation related to follow-up management such as administrative litigation regarding a business suspension order following a field survey on nursing homes and the resulting adjustments of the upper limit and eligibility for benefits. Over the last two years of his public service, he worked as an administrative official at the Division of Pharmaceutical Benefits in collaboration with the Health Insurance Review and Assessment Service and the National Health Insurance Service.

Prior to joining Shin & Kim, Mr. Kim advised clients on pricing & reimbursement at Kim & Chang for 12 years, where he successfully helped numerous domestic and foreign pharmaceutical and medical device companies achieve legal solutions to diverse challenges in responding to health insurance listing/follow-up management of drugs, medical practices and therapeutic materials. He is recognized as an expert with unparalleled knowledge and expertise in the field of healthcare pricing and reimbursement. Based on his in-depth knowledge and extensive administrative experience across the healthcare sector, Mr. Kim also provides extensive advice on country of origin labeling and recognition of manufactured imports in the healthcare industry, such as pharmaceuticals, medical devices, food, cosmetics, etc. and on responding to customs audit related to healthcare, including pharmaceuticals, medical devices, food, and cosmetics.

## 經歷

2023-Present	Shin & Kim LLC
2011-2023	Kim & Chang
2009-2011	Division of Pharmaceutical Benefits, Ministry of Health and Welfare
2008-2009	Division of Healthcare Resources, Ministry of Health and Welfare
2005-2008	Division of Regulatory Reformation and Legislation, Ministry of Health and Welfare
2003	Judicial Research & Training Institute of the Supreme Court of Korea

### Professional Affiliations

2024-Present	Member, Regulation-Free Special Zone Ombudsman, Ministry of SMEs and Startups
2013-2016	Director, Childcare Center Safety and Insurance Association, Ministry of Health and Welfare
2013-2016	Member, Long-term Care Examination Committee
2013-2016	Member, Communication Advisory Committee, Ministry of Food and Drug Safety
2013-2016	Member, Institutional Review Board, Kangbuk Samsung Hospital
2012-Present	Member, Customer Satisfaction Management Advisory Committee, Health Insurance Review and Assessment Service
2012-2016	Member, Deliberative Committee on Publication of the List of Workplace Child Care Centers
2011-Present	Director of Legislation, Korea Association for Oral Health

## 主な実績

### Pricing & Reimbursement

- General advice on insurance listing of new drug premium price, including environmental shaping strategy
- General advice on insurance listing of new anticancer/rare disease drugs subject to RSA
- General advice on design of RSA types
- General advice on insurance listing of new anticancer/rare disease drugs subject to exemption from economic evaluation
- General advice on expansion of benefit standards of listed new drugs
- General advice on renewal of anticancer drugs and rare disease medicine subject to RSA
- General advice on expansion of benefit standards during the term of RSA
- General advice on overlapping application of drug price follow-up management mechanisms
- General advice on NHIS's strategy for price and volume negotiation
- General advice on NHIS's price-volume agreement
- General advice on NHIS's preparation of drug price agreement and risk sharing agreement

- Analysis of legal issues in disposition of reducing drug price subject to price increase reevaluation and general advice on procedures for filing objection
- General advice on response to disposition of delisting as a result of healthcare benefit appropriateness evaluation
- General advice on disputes arising from interpretation of biosimilar/IMD price calculation criteria
- General advice on a strategy for transfer of pharmaceutical products related to M&A of pharmaceutical companies
- General advice on NECA procedures regarding new health technology evaluation and innovative health technology evaluation for medical devices
- General advice on insurance listing of Korea's first innovative health technology
- General advice on insurance listing of NGS-CDx
- General advice on a strategy for acknowledgement of separate medical fees for medical practice using AI-based software
- General advice on response to disposition of reducing the maximum price as a result of therapeutic material cost survey
- General advice on preliminary benefit (selective benefit) reevaluation process

#### **Interpretation of Authority with Regard to Healthcare Laws and Regulations**

- General advice on applications for authoritative interpretation regarding violations of the Medical Service Act
- General advice on applications for authoritative interpretation regarding violations of the Pharmaceutical Affairs Act and the Medical Devices Act

#### **Litigation**

- Lawsuit seeking revocation of disqualification/suspension of medical license
- Lawsuit seeking revocation of disposition of suspension/fines against medical care institutions for false, unreasonable claims
- Lawsuit seeking revocation of disposition of reducing drug price involving kickback payments
- Lawsuit seeking revocation of disposition of reducing original drug price due to the release of generic drug
- Lawsuit seeking revocation of disposition of reducing drug price subject to price increase reevaluation
- Lawsuit seeking revocation of disposition of delisting as a result of healthcare benefit appropriateness evaluation
- Lawsuit seeking revocation of disposition of changing healthcare benefit standards
- Lawsuit seeking revocation of administrative disposition for violation of the Pharmaceutical Affairs Act, the Medical Devices Act and the Act on In Vitro Diagnostic Medical Device.

#### **Establishment of Non-Profit Corporation**

- General advice on the establishment of non-profit corporations

- General advice on response to regular audit on non-profit corporations

## 学歴

2025	KAIST Advanced Bio Health Innovation Program
2024	Yonsei University Graduate School of Public Health, Advanced Program "Future and Regulatory Science of BioHealth"
2018	Seoul National University, Science & Policy Advanced Research Course
2015-2016	UC Berkeley School of Law, Visiting Scholar
2009-2011	Seoul National University Graduate School of Public Health (M.A. coursework completed)
1990-1996	Sungkyunkwan University College of Law (LL.B.)

## 資格

2003	Admitted to bar, Korea
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## 言語

Korean, English

## 主な活動

- Asia Business Law Journal – A comparison of healthtech regulatory issues in North Asia: Korea (February 2024)

## 受賞経歴

2007	Commendation, Minister of Health and Welfare
2007	Commendation, Chief Prosecutor of Seoul High Prosecutors' Office

## 外部評価

- "Best Lawyer" for Health Care & Bio, JoongAng Ilbo, Korea In-house Counsel Association, 2023

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