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SUMMARY OF HEALTH CARE REFORM CHANGES

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (together, the "Act"), effects significant changes to numerous aspects of health care delivery. As such, this summary is intended to provide only an immediate, broad overview of certain provider-related issues contained in the Act. Depending on the type of provider and other unique circumstances, there may be additional provisions contained in the Act which may be of interest to you.

For your convenience, we have categorized the Act provisions into four major sections—1) quality initiatives, 2) program integrity reforms, 3) payment reforms, and 4) pilot programs and demonstration projects—and provided sub-titles for each category. Summaries of other legislative provisions beyond these topics, including tax and employment issues, will be forthcoming in separate advisories. This summary is not intended to provide legal advice. You should seek counsel on any specific issue or question you might have on this legislation.

QUALITY INITIATIVES

- Hospital Payment Linked to Quality. The Secretary of the Department of Health and Human Services ("Secretary") is required to implement regulations, effective July 1, 2011, that prohibit Medicaid payments to states for any amounts expended in providing medical assistance for health care-acquired conditions specified in the regulations. Effective FY 2013, Medicare payments to hospitals will be reduced to account for excess hospital readmissions for certain conditions. The Act also directs the Secretary to make certain hospital readmission rates available to the public. Beginning FY 2015, those hospitals demonstrating a high rate of hospital-acquired conditions will be subject to a 1% payment penalty for certain discharges.
- Value-Based Purchasing Programs. Beginning FY 2013, the Secretary must establish a hospital value-based purchasing program, under which value-based incentive payments are made to hospitals that meet performance standards for quality measures related to common and high-cost conditions, including acute myocardial infarction, heart failure, pneumonia, surgeries, and healthcare-associated infections. The Secretary is also directed to develop similar value-based purchasing programs for skilled nursing facilities, home health agencies, and ambulatory surgical centers. The Secretary must provide periodic reports on the development of these programs to Congress beginning January 1, 2011.
- Shared Savings Program and Accountable Care Organizations. No later than January 1, 2012, the Secretary must establish a shared savings program that promotes accountability for patient populations, coordinates items and services provided under Medicare, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Under the program, groups of providers and suppliers will be authorized to form accountable care organizations ("ACOs") to manage and coordinate care for Medicare beneficiaries. ACOs that meet the quality performance standards established by the Secretary will be eligible to receive a percentage of the funds generated under the shared savings program.





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- Quality Reporting Programs and Measures. Beginning FY 2014, the Secretary will require long-term care hospitals, inpatient rehabilitation hospitals, hospice programs, PPS-exempt cancer hospitals, and psychiatric hospitals and units to submit data on certain quality measures. The Secretary will penalize providers who do not participate in this reporting program through a reduction in annual payment updates.
- Center for Medicare and Medicaid Innovation. The Secretary is directed to create an Innovation Center within CMS to test innovative payment and service delivery models designed to reduce program expenditures while preserving quality care. The Center must be established by January 1, 2011.
- Physician Quality Reporting Initiative and Physician Feedback Program. The Act extends through 2014 the Physician Quality Reporting Initiative ("PQRI"), a program which provides incentives to eligible professionals who report quality data to Medicare. Beginning FY 2011, the Act provides for an additional 0.5% Medicare incentive payment for eligible professionals who report quality measures through the new Maintenance of Certification program. Effective FY 2014, the Act provides for a 1.5% Medicare payment reduction, increased to 2.0% in FY 2015, for eligible professionals who do not submit measures to the PQRI. Finally, the Act expands the current Medicare physician resource use feedback program to provide for the development of individualized, risk-adjusted and areastandardized reports comparing per capita physician utilization by 2012.
- Value-Based Physician Payment Modifier. Beginning 2015, the Secretary will establish a payment modifier that provides for differential payment to a physician or a group of physicians under the physician fee schedule based upon the quality of care furnished compared to cost during a specified performance period.
- **Performance Information on** *Physician Compare* **Website.** By 2011, the Secretary will develop a "Physician Compare" website where Medicare beneficiaries can compare care quality and patient experience information.
- GME and IME Changes. The Act provides that, for the purpose of graduate medical education and indirect medical education calculation, all the time spent by a resident or intern in a non-provider setting will be counted towards the determination of full-time equivalency, if the hospital incurs the costs of the stipends and fringe benefits of the resident or intern during that time. (Effective July 1, 2010) If multiple hospitals incur costs, the hospitals must count a proportional share of the resident training time, determined by written agreement between the hospitals. The Act requires that any hospital that intends to claim time spent in a non-provider setting maintain and make available to the Secretary certain records regarding the amount of such time. Additionally, the Act provides that all time spent by an intern or resident in certain non-patient care activities, such as didactic conferences and seminars and on vacation, sick leave, or other approved leave, as part of an approved medical residency training program, will count toward the determination of full-time equivalency, subject to certain requirements.
- **Redistribution of Residency Positions.** Effective July 1, 2011, the Secretary must redistribute certain previously unfilled residency positions and direct those slots for training of primary care physicians, giving special preference to programs in states with a low physician resident to population ratio and to programs located in states with a high health professional shortage to population ratio.





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PROGRAM INTEGRITY REFORMS

- Provider Screening and Other Enrollment Requirements. The Act authorizes enhanced screening of existing and new providers and suppliers; a provisional period of enhanced oversight for new providers, including prepayment review and payment caps; additional disclosure requirements related to a provider's current or previous affiliations with providers that have uncollected debt or have been excluded or suspended from a federal health care program; potential temporary enrollment moratoria; and the requirement that Medicare and Medicaid enrolled providers establish compliance programs containing certain "core elements" to be established by the Secretary. Particularly, if the Secretary determines that there is a significant risk of fraudulent activity among durable medical equipment suppliers, payment may be withheld for 90 days beginning on the day that the provider submits its claim.
- The Anti-Kickback Statute. The federal anti-kickback statute, at 42 U.S.C. 1320a-7b, has been revised to provide that a claim for items or services originating from a violation of the statute also constitutes a false claim under the False Claims Act. The Act further provides that a person need not have actual knowledge of the anti-kickback statute or specific intent to commit a violation of the statute to be found liable under its provisions.
- Return of Overpayments. The Act requires a person who has received an overpayment to report and return the payment within 60 days after identification of the overpayment or by the date the corresponding cost report is due, whichever is later. The Act also clarifies that the retention of an overpayment after this deadline constitutes an "obligation" for purposes of False Claims Act liability with the result that retention may subject the provider to treble damages and penalties.
- False Claims Act Public Disclosure Bar and Whistleblower Protections. The Act revises the False Claims Act "public disclosure" jurisdictional bar to give the government the power to veto a defense motion to dismiss a *qui tam* action that is based on publicly disclosed information. It also broadens the "original source" exception to the public disclosure bar by eliminating the requirement that a *qui tam* relator possess "direct" knowledge of the information on which the allegations are based. Finally, the Act adds protections from retaliation and discrimination for whistleblowers.
- Enhanced Civil Monetary Penalties. The Act provides enhanced civil monetary penalties of up to \$15,000 per day for providers who fail to give the Inspector General timely access to documents for the purpose of audits, investigations, evaluations, or other statutory functions of the Inspector General. The Act also provides for enhanced civil monetary penalties of up to \$50,000 per violation for providers who knowingly make, use, or cause to be made or used any false statement to a federal health care program.
- Physician Ownership of Hospitals. The Act places strict ownership prohibitions and facility expansion limits on new and existing physician-owned hospitals. First, to qualify for the rural provider and "whole hospital" exceptions to the Stark prohibition, the hospital must have physician ownership or investment and a provider agreement in place by December 31, 2010. Hospitals with existing physician ownership are prohibited from increasing the percentages of the ownership interests held by physicians or increasing the number of operating rooms, procedure rooms, and beds with certain limited exceptions. The Act also requires physician-owned hospitals to submit an annual report to the





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Secretary disclosing its owners and the extent of each owner's interest. The Secretary must establish policies and procedures to ensure compliance with these requirements and may include unannounced hospital site reviews in such policies and procedures.

- Stark In-Office Ancillary Services Exception. Effective January 1, 2010, the Act amends the Stark Law to require those providers who satisfy the in-office ancillary services exception to inform patients in writing at the time of a referral for magnetic resonance imaging, computed tomography, positron emission tomography, and any other designated health service that the Secretary determines appropriate, that the individual may obtain the services from other individuals. The Act also requires the provider to furnish the patient with a list of suppliers who furnish the same services in the local area.
- Stark Self-Referral Disclosure Protocol. The Act directs the Secretary to establish and publish a protocol to enable providers to self-disclose Stark Law violations. The Act also authorizes the Secretary to reduce the amounts owed for Stark violations based on the nature and extent of the improper or illegal practice, the timeliness of the disclosure, the cooperation in providing additional information related to the disclosure, and such other factors as the Secretary considers appropriate.
- Permissive Exclusions and Civil Monetary Penalties. The Act gives the Secretary discretion to exclude from participation in federal health care programs any individual or entity who knowingly makes a false statement, omission, or misrepresentation of a material fact in an application, agreement, bid, or contract to enroll or participate in a federal health care program. The Act also provides for enhanced civil monetary penalties of up to \$50,000 per violation for any individual or entity who orders or prescribes an item or service while excluded from a health care program and knows or should have known that a claim would be made for the item or service under the program, makes a false statement, omission, or misrepresentation of material fact on an application, bid, or contract to participate or enroll in a federal health care program, or who knowingly retains an overpayment.
- Nursing Home Transparency and Improvement. The Act requires all Medicare and/or Medicaid certified nursing facilities to make available on request by the Secretary, the Office of the Inspector General, the State, or the State's ombudsman, information regarding the organizational structure, the governing body, officers, directors, members, partners, trustees, and managing employees, as well as additional disclosable parties. The Act now requires the administrator of a certified nursing facility to provide notice to the Secretary, the State, and the facility residents of the impending closure of the facility no less than 60 days before closure. The notice must include a plan for the transfer and relocation of each facility resident, prior to the closure, to the most appropriate facility or setting, subject to the needs, choice, and best interests of the resident. The administrator must ensure that the facility does not admit any new residents on or after the date the facility provides such notice. The Act further directs the Secretary to develop a standardized complaint form for use by residents or their representatives and directs each state to establish a complaint resolution process. Finally, the Act authorizes the Secretary to reduce penalties up to 50% for nursing facilities in certain cases where the facility self-reports and promptly corrects certain deficiencies.





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- Expansion of RAC Program. No later than December 31, 2010, each state must establish a program through which it contracts with one or more recovery audit contractors to identify underpayments and overpayments and recoup overpayments for all Medicaid services. Additionally, the Secretary is required to expand the RAC program to Medicare Parts C and D by December 31, 2010.
- Community Mental Health Centers. The Act now requires community mental health centers that provide partial hospitalization programs to furnish at least 40% of services to individuals who are not eligible for Medicare and in a setting other than an individual's home or an inpatient or residential setting, effective one year from enactment of the Act.
- DME and HHA Order Requirements. The Act requires that a physician or eligible professional be enrolled in Medicare before ordering durable medical equipment for a beneficiary. Additionally, the Act requires that a physician who orders home health services be enrolled in Medicare. The Act also requires a face-to-face encounter (including telehealth) with a practitioner prior to certification of a patient's eligibility for Medicare home health services or durable medical equipment. For home health services, a physician, nurse practitioner, clinical nurse specialist, certified nurse-midwife, or physician assistant may perform the face-to-face encounter. For durable medical equipment, only a physician, physician assistant, nurse practitioner, or clinical nurse specialist may perform the encounter.
- Health Care Fraud and Abuse Control Account. The Act increases funding for the Health Care Fraud and Abuse Control Account by \$250 million through FY 2016 and indexes funds based on the Consumer Price Index increase.
- **Drug Manufacturer Transparency.** Beginning March 31, 2013, the Act requires drug, device, biological, and medical supply manufacturers to report annually to the Secretary any payment or transfer of value made to a physician, medical practice, group practice, and/or a teaching hospital, as well as any ownership or investment interest (excluding an interest in a publicly traded security and mutual fund) held by a physician or a physician's immediate family member. The Act also requires each manufacturer and authorized distributor of record of an applicable drug to report certain information related to drug samples.
- Other Program Integrity Provisions. The Act reduces the maximum period during which a claim may be submitted to Medicare from three years to 12 months from the date the services are furnished. The Act gives the Secretary the discretion to require DME suppliers, home health providers, and other providers or suppliers to furnish surety bonds in varying amounts based on the level of risk involved with the provider and to suspend payments to a provider pending an investigation of fraud. The Secretary has the authority to dis-enroll physicians or suppliers who fail to maintain and provide access to written orders for DME, home health services, or referrals for other items or services for programs at high risk of waste and abuse. The Act also gives the Secretary the power to issue subpoenas and require the attendance and testimony of witnesses and the production of evidence related to matters under investigation by the Secretary. Finally, the Act provides for increased data sharing among federal agencies for the purpose of identifying fraud and waste, as well as increased funding to combat fraud and abuse.





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PAYMENT REFORMS

- Revisions and Adjustment to Annual Market Basket Updates, Wage Index. The Act revises the annual market basket updates for inpatient acute hospitals, skilled nursing facilities, long-term care hospitals, inpatient rehabilitation facilities, home health agencies, psychiatric hospitals, hospice care, dialysis, outpatient hospitals, ambulance services, ambulatory surgical center services, laboratory services, certain durable medical equipment, prosthetic devices, orthotics, and prosthetics, and certain other items. In certain cases, the Act also calls for the incorporation of productivity improvements into market basket update adjustments. Finally, the Act requires the Secretary to submit a plan to reform the hospital wage index.
- Reductions to Medicare and Medicaid Disproportionate Share Hospital ("DSH") Payments. Effective FY 2014, the Act reduces Medicare DSH payments to all eligible hospitals, but also adjusts the payment based on a calculation involving several factors, including the hospital's uninsured population and the amount of uncompensated care provided. Beginning FY 2014, the Act reduces Medicaid DSH payments by \$18.1 billion over seven years. The Secretary is required to develop a methodology to distribute the DSH reductions in a manner more fully described in the Act.
- Payments for Qualifying Hospitals. The Act makes available \$400 million from the Federal Hospital Insurance Trust Fund for payments to qualifying hospitals in FYs 2011 and 2012. A qualifying hospital is a subsection (d) hospital, as defined by \$1886(d)(1)(B) of the Social Security Act, located in a county that ranks, based upon ranking in age, sex, and race adjusted spending for benefits under Medicare Parts A and B per enrollee, within the lowest quartile of such counties in the United States.
- Payments to Rural Providers. The Act extends Medicare payment of reasonable costs for certain clinical diagnostic laboratory tests furnished to hospital patients in certain rural areas for one year beginning July 1, 2010, and provides for temporary improvements to the Medicare inpatient hospital payment for certain low-volume hospitals. Finally, in general, the Act charges MedPAC with reviewing the adequacy of payments for items and services furnished to Medicare beneficiaries in rural areas, as well as analyzing payment adjustments, access by Medicare beneficiaries, payment adequacy, and the quality of care furnished in rural areas.
- Additional Requirements for 501(c)(3) Hospitals. To be treated as a 501(c)(3) tax exempt organization, hospitals must now comply with additional requirements including: (1) conducting a Community Needs Assessment every three years; (2) implementing a financial assistance policy; (3) setting limitations on charges; and (4) instituting certain debt collection practices.
- Payment Reform for HHAs. Effective FY 2014, the Secretary must rebase payment amounts to home health agencies based on certain factors, including changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other factors that the Secretary considers to be relevant. In conducting the analysis, the Secretary may consider differences between hospital-based and freestanding agencies, between for-profit and nonprofit agencies, and between the resource costs of urban and rural agencies. The adjustment will be phased in over four years with full implementation





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in FY 2017. The Act also provides that the Secretary must conduct a study on home health agency costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and in treating beneficiaries with varying levels of severity of illness. The Secretary may, as determined appropriate, provide for a demonstration project to test whether making payment adjustments for home health services under the Medicare program would substantially improve access to care for patients with high severity levels of illness or for low-income or underserved Medicare beneficiaries.

- Payment Reform for Hospice Providers. No later than January 1, 2011, the Secretary must collect appropriate data to revise payments for hospice care. Some examples of the type of data that may be collected include charges and payments, the number of days of hospice care attributable to Part A beneficiaries, charitable contributions and other revenue of the hospice program, the number of hospice visits, the type of practitioner providing the visit, and the length of the visit. The Act adopts the "MedPac Hospice Program Eligibility Recertification" recommendations, which require a physician or nurse practitioner to have and attest to a face-to-face encounter with a patient to determine continued eligibility for hospice prior to the 180th-day and each subsequent recertification. The Act requires medical review of hospice care for certain beneficiaries receiving hospice care for more than 180 days.
- Payments to Physicians. The Act extends the work geographic index floor and revises the practice expense geographic adjustment under the Medicare physician fee schedule. The Act also extends the physician fee-schedule mental health add-on through December 31, 2010, and requires certain changes to Medicaid payment rates for certain primary care services furnished by a physician with a primary specialty designation of family medicine, general internal medicine, or pediatric medicine. For Medicare services furnished by a primary care practitioner between January 1, 2011, and January 1, 2016, the Act provides for an additional 10% payment to the practitioner. Finally, the Act directs the Secretary to identify periodically services as being potentially under or over valued and review and adjust the relative values of those services.
- Establishment of Independent Payment Advisory Board. The Act creates the Independent Payment Advisory Board. The purpose of this section, in accordance with the provisions of the section, is to reduce the per capita rate of growth in Medicare spending.
- 340B Program. The Act expands the list of covered entities receiving 340B discounted drug prices to include certain PPS-excluded children's hospitals, PPS-excluded cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. Additionally, the Act provides for 340B program integrity improvements, through manufacturer and covered entity compliance requirements and the establishment of an administrative dispute resolution process. The Act further requires the Comptroller General to examine and make recommendations as to whether those individuals served by the covered entities under the 340B program are receiving optimal health care services, no later than 18 months after the enactment of the Act.

PILOT PROGRAMS AND DEMONSTRATION PROJECTS

• Medical Home Grants and Medicaid Health Home Option. The Secretary must create a program to provide grants or enter into contracts with eligible entities to establish community-based interdisciplinary, interprofessional teams to





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support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entity. Grants or contracts must be used to establish health teams to provide support services to primary care providers and to provide capitated payments to primary care providers, as determined by the Secretary. Beginning in 2011, states will have the option as a state plan amendment to provide for medical assistance to eligible individuals with chronic conditions who elect a designated provider as described in the Act as the individual's health home for the purposes of providing the individual with health home services.

- Payment Bundling Pilot Programs. No later than January 1, 2013, the Secretary must establish a pilot program for payment for integrated care during an episode of care provided to an applicable beneficiary around a hospitalization to improve the coordination, quality, and efficiency of health care services. Among other items in the Act, the Secretary must develop payment methods for the pilot program, which may include bundled payments or bids from entities for episodes of care.
- Medicare Hospice Concurrent Care Demonstration Program. The Secretary must establish a Medicare Hospice Concurrent Care demonstration program at participating hospice programs under which Medicare beneficiaries are furnished, during the same period, hospice care and any other items or services covered under Medicare from funds otherwise paid under Medicare to such hospice programs. The Secretary must provide for the conduct of an independent evaluation, which determines whether the program has improved patient care, quality of life, and cost-effectiveness for beneficiaries. The Secretary must submit to Congress a report containing the results of the evaluation, together with such recommendations as the Secretary determines appropriate.
- Rural Demonstration and Grant Programs. The Act extends the Rural Community Hospital Demonstration Program and the Medicare-dependent hospital program, refines the existing rural community health integration model demonstration project, and extends and revises the Medicare Rural Hospital Flexibility Program.
- Pay-for-Performance Pilot Testing. No later than 2016, the Secretary must test value-based purchasing programs under Medicare for psychiatric hospitals and units, long-term care hospitals, rehabilitation hospitals, PPS-exempt cancer hospitals and hospice providers.
- Medical Tort Litigation Alternatives Demonstration Project. The Act authorizes demonstration grants to states for
 the development, implementation, and evaluation of alternatives to current tort litigation involving injuries allegedly
 caused by health care providers or health care organizations.
- New Medicaid Demonstration Projects. Beginning January 1, 2012, the Secretary must establish a four-year demonstration project to evaluate the use of bundled payments for the provision of integrated care for a Medicaid beneficiary with respect to an episode of care that includes a hospitalization and for concurrent physicians services provided during a hospitalization. For FYs 2010–2012, the Secretary must establish the Medicaid Global Payment System Demonstration Project which requires certain selected states to adjust the payments made to an eligible safety net hospital system or network from a fee-for-service payment structure to a global capitated payment model. Effective FY 2011, the Secretary must establish a demonstration project under which an eligible state shall provide payment under the state Medicaid plan to certain institutions for mental diseases for the provision of medical





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assistance available under such plan to individuals who have attained age 21 but have not attained age 65 and who require assistance to stabilize an emergency medical condition. The Secretary shall establish the Pediatric Accountable Care Organization Demonstration Project to authorize a participating state to allow pediatric medical providers that meet specified requirements to be recognized as an accountable care organization for purposes of receiving incentive payments in the same manner as an accountable care organization is recognized and provided with incentive payments under the Medicare shared savings program discussed previously in this summary.

- Miscellaneous Demonstration Programs. The Act authorizes (or in some cases, reauthorizes) demonstration programs to:
 - Provide grants to certain entities or consortia to integrate quality improvement and patient safety into health professional clinical education curricula;
 - Improve immunization coverage;
 - Provide funding for certain community health centers to provide comprehensive risk-factor assessments and individualized wellness plans to at-risk populations;
 - Provide funding for the employment and training of recent nurse practitioner graduates for careers as primary care providers in federally qualified health centers and nurse-managed health clinics;
 - Provide funding to eligible hospitals to pay the hospital's reasonable costs incurred in providing qualified clinical training to advance practice nurses;
 - Implement a national independent monitor program to conduct oversight of skilled nursing facility chains;
 - Develop best practices in culture change and for the use of information technology to improve resident care in skilled nursing facilities and nursing facilities;
 - Provide access to comprehensive health care services to the uninsured for a reduced fee;
 - Test a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care teams designed to reduce expenditures and improve health outcomes in the provision of items and services for certain Medicare beneficiaries;
 - Extend and provide additional funding to the current gainsharing demonstration program which tests and evaluates methodologies and arrangements between hospitals and physicians designed to govern the utilization of inpatient hospital resources and physician work to improve the quality and efficiency of care provided to Medicare beneficiaries and to develop improved operational and financial hospital performance with sharing of remuneration; and
 - Assess the impact of separate payments for certain complex diagnostic laboratory tests.





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As noted above, this summary is not intended to provide legal advice and is being distributed solely to provide a general overview of certain provider-related issues contained in the Act Additional summaries on other legislative provisions, including tax and employment, will be forthcoming. If you have any questions or would like further information on any of the Act provisions, please contact **Myla R. Reizen** at (305) 679-5716 or **Neely S. Griffith** at (504) 582-8450.

—Myla R. Reizen and Neely S. Griffith





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Remember that these legal principles may change and vary widely in their application to specific factual circumstances. You should consult with counsel about your individual circumstances. For further information regarding these issues, contact:

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