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ABSTRACT

Increasing patient and therapeutic complexity have created both challenges and opportunities for heart failure care. Within this background, the coronavirus disease-2019 pandemic has disrupted care as usual, accelerating the need for transition from volume-based to value-based care, and demanding a rapid expansion of telehealth and remote care for heart failure. Patients, clinicians, health systems, and payors have by necessity become more invested in these issues. Herein we review recent changes in health care policy related to the movement from volume to value-based payment and from in-person to remote care delivery. (J Cardiac Fail 2022;28:835–844)

Key Words: heart failure, value-based care, telehealth, payment models.

The care of patients with heart failure (HF) is both clinically and economically challenging in modern practice. Clinicians, health systems, payors, and patients are all having to adjust to the increasing clinical and therapeutic complexity of HF as care moves from being volume-based to value-based care. Over the past 10 years, patients have become more complex, with greater numbers of comorbidities. To add to these challenges, the coronavirus disease 2019 (COVID-19) pandemic led to a dramatic short-term decrease in outpatient visits that was addressed in part by an even more dramatic increase in virtual visits. This expanded use of telemedicine was facilitated by policy changes implemented by the Centers for Medicare & Medicaid Services and many other payors, as well as by the availability and rapid use of virtual platforms. Hospitals and clinics quickly found that they needed to manage patients in a nontraditional way, that is, at a distance. The changes that occurred in telehealth would have ordinarily taken years to be a reality. Yet in the midst of the pandemic, services were accelerated by the need imposed on the systems.

These issues were addressed at the fifth annual symposium entitled “Managing the Economic Challenges in the Treatment of Heart Failure” convened at the 2020 Heart Failure Society of America Annual Scientific Meeting to discuss postpandemic challenges and changes in 2 areas of US health care policy. First, value-based care was explored, including how the increasing complexity of patients with HF and in available pharmacotherapies demand a more integrated and value-conscious approach; how systems of payment are evolving to motivate evolution of care delivery; how the Yale New Haven Health system provides an example of these changes; and how patient health outcomes are likely to improve if these changes are well executed. Second, telehealth was explored, including US regulatory definitions of remote care; potential benefits of expanded telehealth as part of value-based care; COVID pandemic acceleration of telehealth uptake; and policy changes needed to sustain telehealth implementation. This review was inspired by the content of the symposium and subsequent developments in the field.

Navigating the Complexities in Patients With HF to Meet the Value Imperative

Three contemporaneous shifts are currently impacting HF care: the increasing clinical complexity of
patients; the increasing therapeutic complexity of managing patients, particularly those with HF with reduced ejection fraction (HFrEF); and continued changes in health care system delivery and financing.

Increasing Complexity

The increase in clinical complexity of HF is illustrated in a large, population-based study of temporal trends and patterns in HF incidence in the United Kingdom from 2002 to 2014, which showed a substantial increase in clinical comorbidities during that time.3 The mean number of comorbidities increased from 3.4 to 5.4, with anemia, chronic kidney disease, diabetes, atrial fibrillation, hypertension, and ischemic heart disease among the most common comorbidities at the time of HF diagnosis. Similar findings were reported in an analysis of the Get With The Guidelines-HF registry in the United States.4 Not surprisingly, this increased clinical complexity is accompanied by increased health care expenditures. Data on Medicare fee-for-service beneficiaries demonstrate that the 38% of Medicare fee-for-service patients who had 4 or more chronic conditions, which includes patients with HF, accounted for 77% of all Medicare spending in 2017.2

Along with the increased clinical complexity, the pharmacotherapeutic landscape continues to become more complicated, with new classes of agents—such as soluble guanylate cyclase stimulators, sodium glucose co-transporter 2 inhibitors, and cardiac myosin activators—joining an already crowded landscape.5,6 Nevertheless, this expanding arsenal for the treatment of HF has been met with enthusiasm because of the potential for improved outcomes. The increasing use of evidenced-based medical therapies for HFrEF has the potential to meaningfully impact clinical outcomes and overall health care use. For instance, in a modeling exercise, the cumulative absolute risk reduction in 2-year mortality if all evidence-based medical therapies (ie, angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker or angiotensin receptor-neprilysin inhibitor; beta blocker; and mineralocorticoid receptor antagonist).12 More staggering is the fact that less than 1% of these patients were on triple therapy at target doses. Whether providers and the health care system are ready to embrace and adopt quadruple therapy, and potentially even more therapeutic complexity, for patients with HF remains to be determined.

Evolution in Payment

Along with increasing clinical and therapeutic complexity, there is a dynamic evolution in the wider ecosystem for health care delivery and payment reform. HF policymakers have continued to work toward decreasing the length of stay, decreasing hospitalizations and readmissions, improving quality and outcomes, decreasing spending, and increasing value. Although policymakers have relatively few avenues to impact payment and delivery reform, the financing of health care is one means of doing so. There has been a movement, particularly within Medicare, away from traditional, fragmented fee-for-service payment models to value-based models of care, such as pay for performance, bundled payments, and accountable care organizations (Fig. 1).13 In these cases, value can best be defined as a ratio of quality—meaning outcomes and patient experience—to cost.

Improving the value of HF care will require an emphasis on clinical outcomes, rethinking the evidence-generation enterprise to meet the needs of various stakeholders, and embracing new models of HF care delivery. Health systems in the United States have invested heavily in traditional brick-and-mortar structures, falling behind on opportunities to leverage new technology to rethink how care is delivered. Providers are accustomed to thinking about process measures of care, and the initial experience with quality improvement and performance improvement has been valuable. Local quality improvement initiatives as well as national quality improvement campaigns around the use of guideline-directed medical therapy among patients with adverse drug reactions, drug–drug interactions, increased risk of medication errors and hospitalization, nonadherence, increased cost, and, most important, decreased quality of life.11

Despite the availability of this pharmacotherapeutic arsenal for HFrEF, there exist significant gaps in the use and dosing of current guideline-directed medical therapy. Data from the Change the Management of Patients with Heart Failure (CHAMP-HF) registry of adult outpatients with HFrEF showed that less than 25% of eligible patients were actually receiving triple therapy (ie, an angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker or angiotensin receptor-neprilysin inhibitor; beta blocker; and mineralocorticoid receptor antagonist). Nevertheless, this expanding arsenal for the treatment of HF has been met with enthusiasm because of the potential for improved outcomes. The increasing use of evidenced-based medical therapies for HFrEF has the potential to meaningfully impact clinical outcomes and overall health care use. For instance, in a modeling exercise, the cumulative absolute risk reduction in 2-year mortality if all evidence-based medical therapies (ie, angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker or angiotensin receptor-neprilysin inhibitor; beta blocker; and mineralocorticoid receptor antagonist). More staggering is the fact that less than 1% of these patients were on triple therapy at target doses. Whether providers and the health care system are ready to embrace and adopt quadruple therapy, and potentially even more therapeutic complexity, for patients with HF remains to be determined.

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reduced ejection fraction HF have been associated with improvements in care patterns. Now it is important to maintain focus on structural and process measures of care while also expanding the focus to clinical outcomes, recognizing their interrelatedness in the Donabedian framework. Recently, the International Consortium for Health Outcomes Measurement defined a standard outcome set for HF. Some of these outcomes are relatively straightforward to capture using traditional administrative or other data streams, such as mortality, readmissions, and length of stay. However, a foundational challenge that must be overcome is the current inability to systematically and accurately capture psychosocial outcomes, functional outcomes, and other patient-reported outcomes that are an integral part of the value equation.

Another foundational challenge for HF care is to strengthen the link from science to evidence to clinical care. For too long, the health care system has been marked by lost opportunities, waste, and harm that have emanated from poorly managed insights, poorly applied evidence, and poorly captured patient experience, such that the potential benefit of a promising therapy is never realized in practice (Fig. 2). The ability to tether science, clinical evidence, and clinical experience together so that the best evidence drives the best care is a fundamental challenge that the system must confront to deliver value.

**Building a Platform to Drive Quality and Value**

As the external environment evolves away from volume-based financing models to value-based models where financial performance is tied much more directly to the quality of care, to the outcomes that are achieved, and the efficiency of care, providers and health systems, as risk-bearing entities, are compelled to reconfigure and reimagine care. Under alternative payment models, guideline-directed medical therapies not only improve patient outcomes (functional and clinical), but also have the potential to generate positive financial gains by decreasing overall health care costs and use. However, there is a pressing need to be able to examine care patterns and test implementation interventions in the course of routine, clinical care.

The Yale New Haven Health System provides an example of these growing capacities. As a large health care system with delivery networks spanning the Interstate-95 corridor in Connecticut, Yale identified the need for a new HF registry that would be embedded within the electronic health record (EHR), provide real-time quality monitoring and a longitudinal trajectory of patients, and would be a foundational resource for implementation science to drive high-quality, high-value care. The Yale Heart Failure Registry was implemented in 2019 and 2020 and is currently tracking and monitoring more than 26,000 patients with HF. It provides real-time views of sociodemographic characteristics, medication use, and many other important clinical characteristics. By being responsive, dynamic, and longitudinal within the EHR, the Yale HF Registry— and others like it across the nation—addresses some of the shortcomings of traditional registries. As another example of the potential, the Yale HF Registry will be used in the Pragmatic Trial of Messaging to Providers About Treatment of Heart Failure.
This randomized, single-blind, interventional trial will test the comparative effectiveness of an EHR-based best practice alert recommending evidence-based, medical therapies approved by the US Food and Drug Administration against usual care in adult outpatients presenting with HFrEF. This trial highlights the ability of a registry that is imbedded within the EHR and driven by routine clinical care—and can also be an engine for future evidence generation, including quality improvement and implementation science—to drive high-quality, high-value care. Other centers are also enacting initiatives. A particularly high-profile and productive example is the Nudge Unit embedded within the Penn Medicine system, as well as integrated health systems like Geisinger. There is important work in quality improvement, shared decision-making, and implementation science that will need to be done as a part of these continued efforts to improve the care of patients with HF and drive value. Health care providers, health systems, integrated delivery networks, and payers will all be asked to drive innovation to bring better outcomes and more efficient care to our patients and to meet the value imperative.

The Value of Value-Based Payment Models

There is real urgency to focus on value in HF, because the burdens are staggering from both a clinical and economic perspective. HF is the number one cause of 30-day readmission among Medicare beneficiaries and the 5-year mortality rate for patients hospitalized for HF is approximately 75%. The total cost of HF (direct and indirect costs in 2010 dollars) was $31.7 billion in 2012 and is projected to increase by 127% to $69.7 billion by 2030, $53.1 billion of which are direct medical costs. Given the relatively high cost and low quality of care in the United States, opportunities to improve value (quality over cost) through improved outcomes and more efficient care are clearly present.

However, one of the main challenges to improving value is accurately capturing and then fairly benchmarking quality. As Peter Drucker famously said, “You can’t manage what you can’t measure.” Although health information technology has helped to capture expenses more clearly, the field of health outcomes measurement remains nascent. Merely checking off a small number of process measures has typically not translated to improvements in patient outcomes such as hospitalization and mortality. Meanwhile, direct measurement of risk-standardized hospitalization and mortality has been criticized for penalizing those who take care of more complex and socially disadvantaged patients and has also been associated with perverse behaviors. The evolution of quality measures, aided by more detailed clinical data capture through the EHR, is an important next step.

A focus on value has several benefits. By prioritizing outcomes and taking a broader view of costs, it aligns the interests of patients, providers, and payors. If there is new drug or a strategy that costs a bit more than the standard of care but is associated with overall decreases in the total cost of care, its use would be a value-dominant strategy. This strategy would be better for patients, providers would...
be eager to adopt it, and payors should embrace it because it leads to better value, better outcomes, better patient experience, and lower overall total costs. In that way, a focus on value promotes the right kind of clinical and operational innovations that are driven by the patient’s experience and outcomes. To bring this about, professional societies should continue to focus on value and advocate for the best evidence-based therapies to be adopted, and all stakeholders involved should come together to discuss the metrics that are important in delivering the best care and value.

HF care is an integral component of value-based models of care (Fig. 1). However, although an increasing proportion of health care dollars are flowing through value-based payment models, no longitudinal models currently focus on chronic HF care. Recently, the Value in Healthcare Initiative’s Value-Based Models Learning Collaborative outlined a call to action to generate and advance new models of value-based care for HF.32 This collaboration developed a framework for a value-based payment model with a longitudinal focus on disease management and prevention, which provides an opportunity to address this gap.

HFSA 2020 Attendees’ Views and Knowledge of Value-Based Care Initiatives

Session participants were surveyed about their experiences and views on these issues throughout the program, with responses (N = 53) comprising physicians (29%), nurses (14%), administrators (14%), and others (43%). Practice settings were inpatient and outpatient (36%), outpatient (24%), inpatient (12%), and other (28%, excluding skilled nursing facilities and long-term nursing facilities). Thirty percent knew their institution was participating in Bundled Payment for Care Improvement Advanced, and 41% were unsure. With regard to quality of care and compensation, the majority (71%) regularly receive individualized reports on the care they provide to patients with HF (eg, quality metrics, length of stay), with part of their compensation being linked to performance on quality or operational metrics. A minority (6%) receive individualized reports that are not linked to compensation, and 24% have a part of their compensation linked to performance without receiving such reports.

Telehealth for HF in the Post–COVID-19 Era

Telehealth, as defined by Medicare’s Health Resources and Services Administration, is the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration (Fig. 3).33 Telemedicine is what is commonly thought of in day-to-day practice as remote clinical services. The technology enabling remote care has expanded rapidly in recent years, including physiologic monitoring (eg, wearables, pacemaker data algorithms, Fig. 3. Telehealth basics. Types of electronic/digital media used in telehealth include videoconferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communication. Mobile and wireless technologies used in mHealth include smartphones, tablet computers, and monitoring devices. mHealth, mobile health.33,34
and pulmonary artery pressure measurement) and communication platforms (eg, videoconferencing, EHR portals, automated transfer of patient data). Uptake has primarily been limited by absence of high-quality data on improved patient outcomes, operational integration, and payment.

Three types of telemedicine services are now being covered by Medicare (Fig. 3). The most common is a telehealth (virtual) visit, which has been used most extensively by clinicians since the emergence of COVID-19. There are also options for virtual check-ins and e-visits (ie, less formal visits for established patients).

**Potential Benefits of Expanded Telehealth**

If done correctly, telehealth can benefit all parties involved in health care delivery. For patients, telehealth can improve access, is convenient, and takes less time, particularly for those who must travel long distances. For clinicians, telehealth can be more efficient, allows participants to focus on communication, and provides the flexibility for physicians to work from the office or from home; during COVID, many payers have set professional fees for telehealth visits equal to in-person visits. For health systems, the short-term loss of facility fees for ambulatory visits converted to telehealth may be viewed unfavorably, particularly by those that have invested in ambulatory care infrastructure; however, over the long term, virtual visits can both decrease overhead for relatively low-profit ambulatory care and allow adjustments in infrastructure to increase capacity for more lucrative procedures and inpatient care. For payors, telehealth can decrease overall payments, because facility fees are decreased, although subscribers get access to the care they need.

To realize these benefits, a number of practical aspects of remote care must be considered and overcome creatively. Experienced in-person assessment of volume and other aspects of the physical examination requires careful replacement with patient-reported symptoms, video evaluation, daily weights, and implantable physiologic monitoring. Laboratory testing, particularly for electrolytes and renal function, ultimately requires person–person contact through home visits or travel to a facility. Future work in telehealth will include regional local laboratories that will provide patient services in person and communicate with the responsible providers. A review of medications with patients must be transitioned to video review, perhaps supplemented by automated prescription (re)fill data. These changes are not trivial to clinician work flow or health system operations, and thus are more likely to garner a commitment to change if reassurances about supportive long-term financial models are in place.

**COVID-19 Pandemic Effects on Telehealth**

The current pandemic has led to significant changes in telehealth-related policy. Table 1 summarizes 5 key policy changes that were implemented by Medicare and many other payors in March 2020 that loosened many restrictions for telehealth use. Of these, perhaps the most significant is the suspension by the US Department of Health and Human Services of many of the Health Insurance Portability and Accountability Act rules around privacy to allow for more flexibility in the use of virtual visit platforms, including those incorporated into EHR software and the one-to-one video platforms that may be familiar to patients and offer a reasonable guarantee of privacy. Establishing electronic connectivity

| Topic                              | Key Policy Changes                                                                 | Implications for Virtual Visits                              |
|------------------------------------|------------------------------------------------------------------------------------|----------------------------------------------------------------|
| Licensing                          | HHS waived the requirement for health care professionals to hold license in the state in which they provide services if they have an equivalent license from another state; HHS asked states to waive local licensing requirements, with the final decision made at the state level | Potentially allows practice of medicine via virtual visits across state lines |
| Privacy                            | HHS suspended HIPAA rules                                                          | Allows use of virtual visit platforms previously deemed not HIPAA-compliant |
| Location of patient                | CMS waived rural and site limitations for telehealth interactions                  | Allows clinicians to be reimbursed for telehealth services regardless of patients’ locations |
| Prior existing relationship        | CMS waived the requirement that telehealth services can be provided only to a clinician’s established patients | Clinicians can see new patients by telehealth services |
| Prescription                       | DEA relaxed rules related to the prescription of controlled substances by telehealth | Clinicians can prescribe controlled substances in the setting of a virtual visit |

CMS, Centers for Medicare & Medicaid Services; COVID-19, coronavirus disease 2019; DEA, Drug Enforcement Administration; HHS, U.S. Department of Health & Human Services; HIPAA, Health Insurance Portability and Accountability Act.
of patients to their health care providers through the EHR corridor is paying dividends not only in telehealth visits, but also in the communication and documentation of those conversations through the EHR. Patients may also be more engaged when they can read their notes and receive their laboratory results immediately.

Relaxation of regulatory requirements to accommodate telehealth has brought about a substantial increase in use. In April 2020, a few weeks after the lockdown went into effect, the percentage of telehealth claims for Medicare, Medicaid, and commercial insurance was 13%, representing an 80-fold increase (0.15%) over the prior year. Interestingly, with the peak of COVID-19 infections decreasing and the relaxation of stay-at-home orders by May 2020, the percentage of telehealth claims decreased to 8.69%. Researchers at Harvard University and Phreesia, a health care technology company, analyzed data on changes in visit volume for the more than 50,000 providers who are Phreesia clients. The data covered more than 12 million visits occurring from mid-February to mid-May 2020. The lockdown began on March 8, 2020, and in-person visits decreased by 60% by March 22. Telehealth visits increased rapidly and remained relatively stable as patients started to resume in-person visits by May. Starting in March 2020, the New York City Health & Hospital System—the largest safety-net health care system in the United States, serving more than 1 million patients annually before the pandemic—increased from fewer than 500 telehealth visits per month to almost 83,000 telehealth visits starting in March, in addition to more than 30,000 behavioral health encounters via telephone and video. This is an example of how a challenged, busy system dramatically transformed the role of telehealth in clinical practice in a short period of time, with COVID-19 as a catalyst for change. The ability of the system to transform ambulatory care in a matter of weeks in the spring of 2020 confirmed that large-scale virtual health care is limited less by technology and more by preferences, policy, and payment.

### Requirements for Sustained Telehealth Expansion

A successful transition to telemedicine requires 3 key elements: (1) access to broadband internet, (2) an internet-capable device, and (3) sufficient technological literacy to take advantage of items (1) and (2). Unfortunately, many people lack one or more of these key elements. In 2019, the Federal Communications Commission estimated that 19 million Americans lacked access to fixed broadband service, with those in rural communities most affected. The Heart Failure Society issued an informative statement early in the pandemic that outlined virtual platforms and models of care, and described aspects such as clinical workflow and preparations for a successful virtual visit, remote monitoring as an adjunct to the visit, and pharmacy considerations. Individual health systems have had to facilitate these changes at the local level. For example, the University of Colorado School of Medicine also issued a White Paper on video visits and improving the patient experience; the paper was distributed to the University of Colorado Health System and contained a wealth of practical information. Ultimately, clinicians need to listen to their patients and continue to be good clinicians and flexible problem solvers, especially when dealing with older patients or the technologically challenged.

The public generally has a positive view of telemedicine. In a nationwide survey conducted by Ipsos on June 20 and 21, 2020, with more than 30,000 respondents, 33% had opted for telemedicine services for their primary health care since the pandemic started and 55% believed it was safer and more accessible. Of those who opted for a telemedicine visit, 42% rated it as very good, 30% as good, and only 8% as not good.

One would expect that no-show rates with telehealth would be lower than in-person visits. Indeed, in a prepandemic, randomized controlled trial conducted at the Cleveland Clinic between October 2018 and July 2019, the observed no-show rate was lower in the group receiving postdischarge virtual visits than among those receiving in-person visits (35% vs 50%, respectively). In contrast, data from the University of Pennsylvania on general and subspecialty cardiology clinic visits over a 1-month period between March and April showed that of 2940 patients scheduled, 46% had a completed telemedicine encounter and 54% had a canceled/no-show visit. Women, non-English speakers, and individuals with lower median household income were less likely to complete a telemedicine visit. As such, clinicians should be careful to not create or exacerbate disparities by using technology and videoconferencing telehealth visits.

Looking ahead, it will be important to collect data on whether patients’ health and health outcomes are helped or harmed by the use of this technology, and to adjust accordingly so that it will be used most appropriately. It will also be important to consider whether allowing individuals with particularly acute needs to be seen by a clinician for the first time via telemedicine instead of in person can result in the best possible outcomes. The right mix of telehealth and in-person visits will need to be tailored to the individual. This process will be especially important for patients with HF.

The use of telehealth has declined from the beginning of the pandemic, but expansion of telehealth is likely here to stay. The COVID-19 pandemic has
forced health care systems to adapt quickly, but it has also been an opportunity to develop new models of care, to proactively engage with patients, and to make health care more accessible.\textsuperscript{45} The Heart Failure Society of America advocates for the continued use of telehealth, noting that “the COVID-19 pandemic has generated an important opportunity to learn about delivering HF care in a different way that should be fully embraced well beyond the current crisis.”\textsuperscript{46} More telehealth visits may be devoted to counseling, medical decision-making, and psychological issues, whereas acute visits for HF decompensation should largely remain in-person. Each clinician, clinic service, and hospital system may have to triage patients with HF into those that can be managed virtually vs those who must be seen in person and—perhaps most difficult—those in between, while keeping value as a target. Policy will need to evolve to accommodate a continued role for telehealth. Medicare’s coverage for many telehealth services is scheduled to end when the COVID-19 epidemic is no longer considered a public health emergency. On April 15, 2021, the US Department of Health and Human Services re-extended the public health emergency for an additional 90 days, so the policy will be revisited in the second half of 2021.\textsuperscript{47} Additional changes in health policy will be required, and several bills have been proposed, such as HR 7663, the Protecting Access to Post-COVID-19 Telehealth Act of 2020.\textsuperscript{48} This bill would authorize Centers for Medicare & Medicaid Services to waive coverage restrictions during national emergencies, allow rural health clinics and federally qualified health centers to serve as the location of the health care practitioner, remove restrictions that require the originating site to be in a rural area, and allow the home of a beneficiary to serve as the originating site for all services. What legislation will ultimately be passed into law remains to be seen; but almost certainly, further changes around telehealth policy and payments are coming.

Conclusions

The COVID-19 pandemic has forced a needed reassessment of policy and payment around the integration of telehealth services and renewed attention to value-based care models within this rapidly changing environment. Patients are becoming more clinically complex, therapeutic complexity has increased (especially in polypharmacy), and options for remote care delivery have been accelerated. Within this setting, there has been a move away from traditional fee-for-service financing models to more value-based models of care. Although changes to structure and process have a clear role, the development of approaches to systematically assess patient-reported outcomes and experience are more vital than ever. Clinicians will need to rethink the evidence generation enterprise to meet the knowledge needs of different stakeholders. Meanwhile, the pandemic has revealed the vast possibilities that telehealth can play in rethinking health care delivery and measurement for patient patients with HF. However, continued telehealth use will require that emergency relaxations of telehealth policies be permanently passed into law. Actual use will depend on health system infrastructure and processes, the way health systems are reimbursed, and the type of care being delivered.

Author contributions

All authors contributed equally to concept and design, interpretation, and critical revision of the manuscript; gave final approval; and agree to be accountable for all aspects of work ensuring integrity and accuracy.

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