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Authors

Shev, Aaron B
Wintemute, Garen J
Cerdá, Magdalena
[et al.](#)

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Prescription Drug Monitoring Program: Registration and Use by Prescribers and Pharmacists before and after Legal Mandatory Registration, California, 2010–2017

Aaron B. Shev, PhD,

Violence Prevention Research Program, Department of Emergency Medicine

Garen J. Wintemute, MD, MPH,

Violence Prevention Research Program, Department of Emergency Medicine

Magdalena Cerdá, DrPH, MPH,

Violence Prevention Research Program, Department of Emergency Medicine

Andrew Crawford, PhD,

Violence Prevention Research Program, Department of Emergency Medicine

Susan L. Stewart, PhD, and

Public Health Sciences–Division of Biostatistics

Stephen G. Henry, MD, MSc

Division of General Medicine, Geriatrics, & Bioethics, School of Medicine, University of California, Davis.

Abstract

Objectives.—To estimate the effect of California’s prescription drug monitoring program’s (PDMP) registration mandate on use of the PDMP.

Methods.—We evaluated the effect of California’s mandatory PDMP registration law by fitting time series models on the percentage of clinicians registered for California’s PDMP and the percentage of clinicians who were active PDMP users (users who created ≥1 patient prescription reports in a given month) from 2010 through 2017. We also compared PDMP use among early PDMP adopters (clinicians who registered >18 months before the mandatory registration deadline) versus late adopters (clinicians who registered ≤18 months before the deadline).

Correspondence should be sent to Aaron B. Shev, Violence Prevention Research Program, Department of Emergency Medicine, UC Davis School of Medicine, 2500 Stockton Blvd, Sacramento, CA 95817 (abshev@ucdavis.edu). Reprints can be ordered at <http://www.ajph.org> by clicking the “Reprints” link.

Contributors

S.I.G. Henry conceptualized the study. A.I.B. Shev and S.I.G. Henry designed the analysis for this work and collected the data. A.I.B. Shev carried out the analysis and took the lead in writing the manuscript in consultation with S.I.G. Henry. All authors provided critical feedback on the analysis plan and the manuscript to help shape the final design of the study and the manuscript.

Human Participation Protection

This study was reviewed by the University of California, Davis institutional review board and was determined to be program evaluation, not human participants research.

Results.—Mandatory registration was associated with increases in active PDMP users: 53.5% increase for prescribers and 17.9% for pharmacists. Early adopters were 4 times more likely to be active PDMP users than were late adopters.

Conclusions.—Mandatory registration was associated with increases in PDMP registration and use, but most new registrants did not become active users.

Public health implications.—Mandatory PDMP registration increases PDMP use but does not result in widespread PDMP usage by all clinicians prescribing controlled substances.

The United States is in the midst of a prescription opioid misuse epidemic. In 2016, approximately 10.9 million American adults reported misusing opioids, defined as taking opioids without a prescription, for reasons other than prescribed, or in larger quantities than prescribed.¹ In the same year, there were 261780 deaths from prescription opioid overdoses, more than quadruple the number in 2000.² Prescription drug monitoring programs (PDMPs)—statewide databases of dispensed prescriptions for scheduled medications that can be used by prescribers and pharmacists at the point of care to check patient prescription histories—have been implemented in 49 states. Clinical guidelines recommend PDMPs as 1 tool for combating overprescribing practices that have contributed to the opioid epidemic.³ Although the evidence is inconsistent, some research has reported reductions in opioid prescribing in states after the implementation of their PDMPs.^{4,5}

A critical barrier to the potential effectiveness of PDMPs has been the low rates of use by prescribers and pharmacists. In 2013, only 1 in 5 prescribers and 1 in 3 pharmacists were registered to use their state's PDMP.⁶ In response to these low rates of PDMP registration, laws mandating registration have been passed in 34 states for prescribers and 26 states for pharmacists⁷; several states have also passed laws mandating PDMP use when controlled substances are prescribed. These laws have been associated with a decrease in the prescribing of Schedule II opioids.⁸ These laws are thought to affect opioid prescribing because increased use of PDMPs results in reduced prescribing to patients at high risk of opioid misuse. However, the outreach and increased awareness of PDMPs that typically accompany enactment of mandatory registration laws may also influence prescribing and dispensing. To our knowledge, no prior study has examined the effect of mandatory registration laws on rates of PDMP registration and use. In this study, we analyze California PDMP registration and utilization data from 2010 through 2017 to evaluate the effects of California's mandatory registration law on rates of PDMP registration and use for prescribers and pharmacists.

This study seeks to identify and measure the extent to which mandatory PDMP registration translates into increased PDMP use and, by extension, explores the potential mechanisms by which mandatory registration may affect prescribing and, ultimately, prescription opioid misuse. It also addresses a common challenge in estimating compliance with PDMP registration and makes recommendations for best practices to address that challenge. Study results will also inform state policy decisions related to PDMPs and provide guidance for states seeking to measure rates of PDMP prescriber registration when linkages between prescriber identity and Drug Enforcement Administration (DEA) number are not available.

METHODS

California established the first PDMP in the United States in 1939. California's PDMP, the Controlled Substance Utilization, Review, and Evaluation System (CURES), introduced a searchable client-facing component in 2009 allowing prescribers and pharmacists to search the database and generate reports of patients' prescription histories. In 2013, funds were provided from the state for CURES to streamline the application process. At the same time, the California Department of Justice implemented further improvements, including automatic patient safety alerts and improvements to patient reports generated in the system. This bundle of updates, known as CURES 2.0, was implemented on January 1, 2016. Mandatory registration went into effect on July 1, 2016 for all clinicians, defined as any prescriber or pharmacist licensed to prescribe or dispense controlled substances in California.

This study used the following data from CURES: prescription records for all Schedule II, III, and IV controlled substances dispensed by California pharmacies; registration dates for all prescribers and pharmacists registered to use the PDMP; and records of user-generated reports of patient prescription histories between 2010 and 2017. Data in the PDMP begin in 2009 and track physicians, pharmacists, dentists, nurse practitioners, physician assistants, and others. A full list can be seen in Appendix A (available as a supplement to the online version of this article at <http://www.ajph.org>). The prescription records reported by pharmacies included drug information, prescriber and pharmacy name, address, and the prescriber DEA number associated with that prescription; prescriber license numbers are not reported. PDMP registration data included prescriber name, DEA number, prescriber license numbers, and clinician registration date. We used PDMP utilization data to calculate the monthly number of patient prescription reports created by each PDMP user. We performed all analyses using R version 3.4.2 (R Foundation for Statistical Computing, Vienna, Austria).

Prescription Drug Monitoring Program Registration

We graphically tracked monthly counts of PDMP pharmacist registrations. We obtained monthly counts of percentage registration compliance by dividing the number of PDMP users registered as "dispensers" by the monthly number of California-licensed pharmacists provided by the California State Board of Pharmacy. The result is an exact calculation of the percentage of registered pharmacists.

For prescribers, we estimated the percentage registered by using a modified version of the method suggested by the PDMP Training and Technical Assistance Center at Brandeis University.⁹ We estimated the percentage of registered prescribers by dividing the monthly number of unique prescribers registered in the PDMP by the number of all unique prescribers, both registered and unregistered, who prescribed any controlled substances during the previous 12 months.

In most states, DEA numbers are the primary prescriber identifier in PDMP prescription data. Measuring compliance with mandatory PDMP registration laws is not straightforward because a single clinic-based DEA number may be used by multiple prescribers working at the same facility, a prescriber who works in multiple facilities may have multiple DEA

numbers, and DEA numbers are not automatically linked to state-issued prescribing licenses. California prescribers with multiple DEA numbers are only required to list 1 DEA number to register with the PDMP, and prescription records reported to the PDMP that use a clinic-based DEA number do not include the prescriber's name. The lack of a 1-to-1 relationship between DEA numbers and state prescribing license numbers creates potential challenges to assessing prescriber compliance with mandatory registration. We therefore compared 3 different methods for tracking prescriber registration to inform "best practices" for states to use when measuring compliance with mandatory registration.

Prescription Drug Monitoring Program Use

We defined PDMP use on the basis of user-generated patient prescription reports. We calculated monthly counts of the total number of reports generated, the number of users generating at least 1 report in a given month, and the average number of reports generated per registered user. To evaluate whether patterns of PDMP use differed between early versus late adopters of the PDMP, we compared patterns of PDMP use among clinicians for early adopters (those who registered prior to November 1, 2015, or 18 months before mandatory registration took effect) versus late adopters (those who registered between November 1, 2015 and July 1, 2016, or <18 months before mandatory registration took effect). We determined the split between early adopters and late adopters using changepoint analysis,¹⁰ a method that estimates the most likely time at which a change in the mean or variance of time series data occurred. For our data, we estimated that this change occurred 8 months prior to the mandatory registration deadline, when PDMP registration began to accelerate.

Data Analysis

Monthly counts of registration and patient report generation following implementation of mandatory registration were displayed graphically and summarized numerically in the tables and figures. We used time series models to estimate the magnitude and statistical significance of the effect of mandatory registration on the percentage of clinicians using CURES at least once in a given month (referred to hereafter as active users), and to measure the difference between the frequency of PDMP use for early versus late PDMP adopters. We analyzed prescribers and pharmacists separately.

We estimated the joint effect of CURES 2.0 updates (widely released in January 2016) and mandatory registration (implemented in July 2016) on the number of registrants, number of active users, and the proportion of registered users who were active users, using autoregressive integrated moving average (ARIMA)¹¹ models fit on data from 2010 through 2015 and a forecast period from January 2016 through July 2016. We parameterized the models to satisfy the assumptions of the model and to minimize Akaike's Information Criterion.¹² We used square root and log transformations on prescriber and pharmacist models of the number of active users, respectively, to satisfy assumptions of the models. We estimated the joint effect of CURES 2.0 and mandatory registration as the difference between the observed values in July 2016 and values forecasted from the ARIMA models for July 2016. The forecasted values predict the counterfactual rates of PDMP registration if CURES 2.0 and mandatory registration had not been implemented. We took the observed values to be fixed population parameters and constructed confidence intervals using the

standard errors from the forecasted values. If the reported 95% confidence interval does not contain 0, this is equivalent to a *P* value of less than .05.

To evaluate differences in clinicians' PDMP usage behavior between early versus late adopter status, we calculated the proportion of registered users who were active users and the mean number of reports generated per user during the 15 months after mandatory registration took effect. We examined population-level data, so we did not use statistical inference to detect differences.

Sensitivity Analysis of Prescriber Registration

To evaluate whether our estimate of the percentage of registered prescribers was close to the true value, we compared 3 alternative estimators for the percentage of registered prescribers using 3 different data sources. The first estimator is described in the Methods section and is used in our primary analysis. For the second estimator, the numerator is the number of physicians registered in the PDMP and the denominator is the number of physicians registered to practice in California multiplied by an estimate of the proportion of practicing physicians in California with a DEA license, which we obtained from a recent statewide survey.¹³ The third estimator is the number of DEA licenses registered in the PDMP divided by the number of DEA prescriber licenses in California reported on the DEA Web site.¹⁴ We tracked all 3 methods monthly between 2010 and 2017. Details of each method are in online Appendix B.

RESULTS

Registration for both prescribers and pharmacists accelerated as the mandatory registration deadline approached. From January to December 2016, the number of registered prescribers increased 174%, from 441413 to 1211895. Over the same period, the number of registered pharmacists increased 63%, from 231752 to 381789.

We observed a corresponding increase in the percentage of prescribers and pharmacists registered for the PDMP (Figure 1). The percentage of registered eligible pharmacists increased from 54.2% in January 2016 to 87.1% in March 2017, with an increase of 14% in the month before mandatory registration was implemented. The percentage of prescribers who were registered increased from 29.5% to 67.2% during the same period, with an increase of 16% in the month before mandatory registration was implemented. The percentage of registered prescribers and pharmacists leveled off immediately following implementation of mandatory registration.

The monthly number of patient prescription reports created in the PDMP increased substantially in 2016 following a trend similar to that seen for registration. The monthly number of patient reports generated by prescribers increased 96% (from 1671793 reports per month to 3281339 reports per month) for prescribers and 39% (from 3421140 reports per month to 4751264 reports per month) for pharmacists from January 2016 to January 2017. Most of this increase occurred in the 6 months between the launch of CURES 2.0 and the mandatory registration deadline in June 2016. Full results are shown in Figure A2 of online Appendix C.

Figure 2 compares the forecasted versus actual counts of registered and active PDMP users and shows that the gap between the number of clinicians registered in the PDMP and the number of active PDMP users (users creating 11 patient report in a given month) widened considerably around the implementation of mandatory registration. The upper (gray) line in each figure represents the number of registered prescribers and pharmacists. The lower (black) line represents active users. Although the ratio of registrants to active users has steadily increased since 2010, this ratio increased rapidly leading up to mandatory registration. In January 2016, 28% of registered prescribers were active users. By July 2016, only 14% of registered prescribers were active users. We observed a similar drop for pharmacists, from 60% to 35%.

Table 1 shows the estimated effect of CURES 2.0 and mandatory registration. We estimated that these changes increased the number of registrants by 101.1% for prescribers and 26.1% for pharmacists and increased the number of active users of the PDMP by 53.5% for prescribers and 17.9% for pharmacists. The time series for active pharmacist users required a log transformation to satisfy model assumptions, resulting in a wider confidence interval. With a much larger increase in registration than in active users, we observed a decrease of over 25% in the proportion of registrants that are also active users. This decrease is also represented in Figure 2 as the widening shaded region.

Table 2 contrasts the usage behavior of early versus late adopters of the PDMP in the 15 months following mandatory registration. We observed large differences between the 2 populations. For both prescribers and pharmacists, early adopters were approximately 4 times more likely than late adopters to be active PDMP users. In the 15 months following mandatory registration, prescriber early adopters generated 56% more reports than late adopters and pharmacist early adopters generated 689% more reports per user than late adopters. Approximately 81.5% of prescribers registered for the PDMP prescribed a controlled substance at least once in the 15 months following mandatory registration.

The sensitivity analysis of the prescriber registration compliance estimator found only small differences in the percentage registered among the method used in our primary analysis and the 2 alternative methods. The average difference between the highest and lowest estimate over all months was 1.3%, and the maximum difference between any 2 estimates was 8.3%. We also found that only 0.1% of prescriptions in the PDMP were prescribed by using a clinic-based DEA number. Thus, estimates of registration based on DEA numbers were not greatly affected by the use of clinic-based DEA numbers. Complete results of this analysis are provided in online Appendix A.

DISCUSSION

Our evaluation of CURES 2.0 and California's mandatory PDMP registration law found that registration increased by 176% for prescribers and 64% for pharmacists from January 2016 to January 2017. Furthermore, the average number of monthly patient reports created increased by 96% for prescribers and 39% for pharmacists during the same period. These results indicate that the law achieved its goal of increasing PDMP registration and use; however, registration was not universal. We estimated that changes to the PDMP were

associated with a 100% increase in registrants for prescribers, but only a 53.5% increase in the number of active users. As a result of registration outpacing the number of active users, the proportion of registrants that used the PDMP at least once in a given month fell by 27.6%. We observed a similar result for pharmacists.

Despite the mandate, registration plateaued at about 67% for prescribers and 87% for pharmacists at the end of our observation period, so there is still potential to increase the percentage registered, especially for prescribers. Following mandatory registration, the percentage of clinicians plateaued, leaving a large percentage of clinicians unregistered for an undetermined reason. Clinicians who remained unregistered may have been retired or not engaged in active practice for some other reason, practicing outside of California, or unaware of the PDMP registration requirement. In a survey of California physicians and pharmacists conducted after implementation of mandatory registration, only 29% of unregistered clinicians reported being aware that registration for the PDMP was mandatory.¹³

Compared with early adopters of the PDMP, late adopters (those who registered within 8 months of the implementation of mandatory registration) were significantly less likely to use the PDMP during a given month and created fewer patient reports per month. This difference persisted for over 1 year after mandatory registration was implemented. The proportion of clinicians creating at least 1 patient report in a given month was about 4 times larger for early adopters of the PDMP than for late adopters, who were more likely to have registered in response to the mandate. One possibility is that many late adopters did not prescribe or dispense controlled substances regularly and so perceived little need to use the PDMP; however, we did find cases of late adopters who prescribed controlled substances and were not active PDMP users.

Our study did not identify the optimal proportion of registered clinicians who should be active PDMP users, but we would not expect all clinicians to use the PDMP regularly. Clinicians who are not in active clinical practice, who do not prescribe or dispense outpatient controlled substances in their practice, or who practice outside of California may rarely have a reason to use the PDMP. Our finding that 18.5% of prescribers who were registered for the PDMP did not prescribe a controlled substance in the 15 months following mandatory registration is consistent with the finding from survey data that 30% of physicians and 24% of pharmacists in California reported that the PDMP was not relevant to their practice, often because they were retired, practiced outside California,¹⁴ or practiced only in inpatient settings.

The problem of estimating percentage registration for prescribers is not unique to California's PDMP and remains a methodological hurdle to assessing and enforcing mandatory PDMP registration in states that do not maintain a comprehensive database that links state prescribing license and DEA license numbers. We calculated the percentage of prescribers with DEA numbers who were registered for the PDMP using 3 different methods and data sources and showed that all 3 methods produced comparable results. As all 3 methods are likely to approximate the true percentage of registered prescribers, we recommend that other states use the method presented in our primary analysis because it can

be calculated using only PDMP prescription data and aligns with existing recommendations.⁹ Although this method is likely to be accurate for evaluating statewide compliance with mandatory registration, assessing compliance at the individual level will require case-by-case analyses when comprehensive databases that reliably link DEA and license numbers do not exist. The California PDMP is currently implementing the collection of state prescribing license number with PDMP prescription data to help address this problem.

Our study had several limitations. Mandatory registration was enacted 6 months after the release of CURES 2.0. One of the main improvements implemented in CURES 2.0 was electronic registration, which removed a major barrier to PDMP usage. Because of this short time interval, we cannot completely separate the effect of this update from the effect of mandatory registration. However, we did follow registration and use rates for 15 months after implementation of mandatory registration, so our estimates of the effects on PDMP use can be considered an upper limit of the potential effect of mandatory registration on PDMP use.

Another limitation is that the PDMP prescription data do not include controlled substances dispensed from federally regulated pharmacies, such as those under the jurisdiction of the Department of Defense and Indian Health Services. Finally, the scope of the study limited our ability to make definitive causal inferences based on the observed association between the mandate and changes in PDMP use patterns. Although it is highly likely that the new registration mandate explains the dramatic increase in PDMP registration immediately prior to that law's implementation, we did not account for other policy changes or programs that may also have increased PDMP usage rates, such as the Centers for Disease Control and Prevention's opioid prescribing guidelines (published March 2016) or contemporaneous efforts in California to promote safe prescribing and decrease opioid-related overdoses. Our study did not examine the effect of mandatory PDMP registration on controlled substance prescribing or opioid misuse; these effects should be investigated in future studies.

This study suggests that, although CURES 2.0 and mandatory registration provide a boost to the number of active PDMP users and an increase in the overall number of PDMP reports created, most clinicians who register shortly before the implementation of mandatory registration will subsequently use the PDMP less than once per month. This finding indicates that mandatory PDMP registration alone is not sufficient to maximize PDMP usage rates. Policymakers pursuing this goal will also need to consider other efforts, such as increased clinician education, or even mandating PDMP use prior to controlled substance prescribing.^{7,14} California requires PDMP use effective October 2, 2018. Although evidence concerning the effect of PDMP policies on overdose death rates is mixed, 2 recent studies found low-strength evidence that mandatory PDMP use was associated with reductions in fatal overdose¹⁵ and reductions in prescribing.¹⁶ This suggests the possibility that the potential benefit of PDMPs is tied not only to access to the PDMP, but also to widespread PDMP usage by clinicians.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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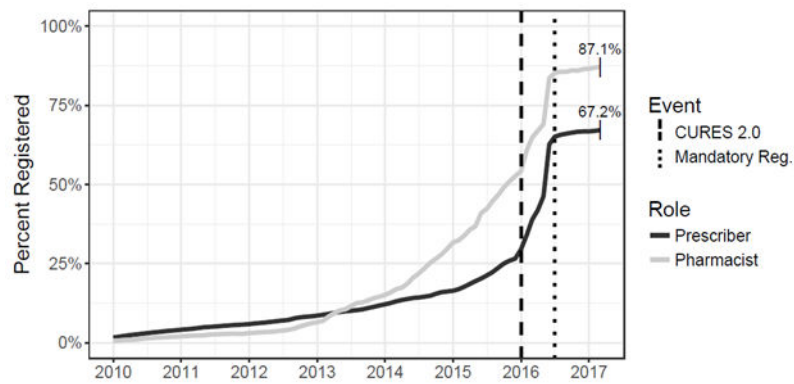


FIGURE 1—
Estimated Monthly Proportion of Eligible Prescribers and Pharmacists Registered With the PDMP: California, 2010–2017

Note. The dashed line and the dotted line indicate the start of CURES 2.0 and mandatory registration, respectively. The annotations above the line indicate the percentage registered in December 2016. PDMP=|prescription drug monitoring program; CURES=|Controlled Substance Utilization, Review, and Evaluation System.

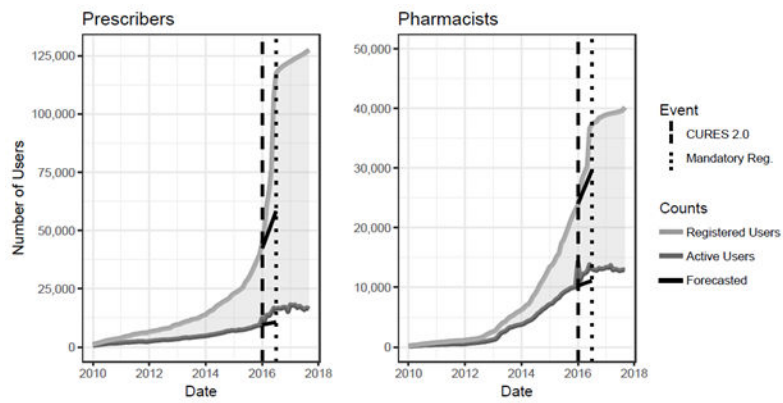


FIGURE 2—

Counts of Registered PDMP Users and Users Who Created at Least 1 Patient Report in a Given Month Among (a) Prescribers and (b) Pharmacists: California, 2010–2017

Note. The dashed vertical line and the dotted vertical line indicate the start of CURES 2.0 and mandatory registration, respectively. The black solid line is the forecasted number of users without CURES 2.0 and mandatory registration from January to July 2016. The scale of the y-axis differs for prescribers and pharmacists. PDMP=|prescription drug monitoring program; CURES=|Controlled Substance Utilization, Review, and Evaluation System.

TABLE 1—

Estimated Joint Effect of CURES 2.0 and Mandatory Registration in Prescription Drug Monitoring Program (PDMP): California, 2010–2017

PDMP User Category	Observed Values (With Changes to PDMP)	Forecasted Values (No Changes to PDMP)	% Difference (95% CI)
Prescribers			
[ems]Registrants	117 487	58 412	101.1 (87.7, 116.6)
[ems]Active users	16 489	10 741	53.5 (41.6, 67.0)
[ems]Active users, %	14.0	19.4	-27.6 (-44.3, 3.2)
Pharmacists			
[ems]Registrants	37 360	29 622	26.1 (18.2, 35.1)
[ems]Active users	13 091	11 103	17.9 (-37.1, 121.8)
[ems]Active users, %	35.0	47.7	-26.5 (-40.8, -3.1)

Note. CURES=Controlled Substance Utilization, Review, and Evaluation System; CI=confidence interval.

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TABLE 2—

Usage Behavior of Early and Late Adopters of California's Prescription Drug Monitoring Program in 15 Months Following Mandatory Registration on July 1, 2016

PDMP User Category	Early Adopters	Late Adopters
Prescribers		
[ems]Registrants	351249	721508
[ems]Active users, %	26.7	6.7
[ems]Reports per user	2.8	1.8
Pharmacists		
[ems]Registrants	211255	151364
[ems]Active users, %	45.8	11.7
[ems]Reports per user	21.3	2.7

Note. Early adopters are clinicians who registered for the PDMP more than 8 months prior to the implementation of mandatory registration; late adopters are clinicians who registered within 8 months of the implementation of mandatory registration. PDMP=|prescription drug monitoring program.

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